OPINION OF ADVOCATE GENERAL
KOKOTT
delivered on 4 June 2020 (1)

Case C-591/16 P

H. Lundbeck A/S and
Lundbeck Ltd
v
European Commission

(Appeal — Competition — Agreements, decisions and concerted practices (Article 101 TFEU and Article 53 of the Agreement on the European Economic Area) — Antidepressant medicinal products — Agreements in settlement of patent disputes entered into by a patent-holding originator undertaking and manufacturers of generic medicinal products — Concept of potential competition — Concept of restriction of competition by object — Fines — Foreseeability of the anticompetitive nature of conduct — Sales to be taken into account for the purpose of calculating the amount of the fine)

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I. Introduction

1. A certain degree of tension is often inevitable between competition and intellectual property rights since, in order to encourage research and development, those rights grant certain exclusive privileges to inventors. That principle also applies to patent law. However, in order to promote technical progress and economic development in general, inventions must, after a period of time, fall into the public domain once patent rights expire so that everyone can make use of them.

2. That latter aspect is of particular importance in the field of medicinal products, where the promotion of research by originator undertakings must be reconciled with the public interest in the marketing of generic medicinal products, which ease the financial burden on health insurance funds and help avoid unnecessary tests on humans and animals. (2)

3. While it is true that, during the validity of a patent, the proprietor has the exclusive right to use his or her invention with a view to manufacturing products and putting them into circulation for the first time as well as the right to oppose infringements, (3) a patent does not afford protection against actions brought to challenge its validity. (4) Therefore, patent disputes between competitors are part of normal competition in sectors where such exclusive rights exist, (5) and it is common practice to resolve or avert such disputes by means of settlement agreements.

4. As the European Commission itself acknowledges in the decision at issue in these proceedings, (6) such patent dispute settlements are in no way unlawful per se and may even be in the public interest as a means of conserving resources and encouraging economic development. However, patent dispute settlements become problematic when they clash with the rules of competition law because their true aim is not to resolve a patent dispute, but to forestall or delay the market entry of potential competitors.

5. In the Commission's view, which was confirmed by the General Court in the judgment under appeal, (7) that was precisely the case in relation to six agreements concerning the antidepressant medicinal product citalopram, entered into by the originator undertaking Lundbeck and several manufacturers of generic medicinal products. In its appeal, Lundbeck challenges that analysis and argues that it is based on a series of errors of law and that the agreements at issue were not such as to attract a penalty under competition law.

6. The present case thus arises in the context of the case culminating in the judgment of 30 January 2020, *Generics (UK) and Others*, (8) in which the Court set out the criteria for determining whether an agreement in settlement of a dispute between the holder of a pharmaceutical patent and a manufacturer of generic medicinal products is contrary to EU competition law, and the 'Servier' cases, currently pending before the Court, in which the Commission found that agreements in settlement of patent disputes infringed EU competition law. (9)

II. Background

A. Facts and administrative procedure

7. H. Lundbeck A/S is a company governed by Danish law which controls a group of companies, including Lundbeck Ltd, established in the United Kingdom (taken together, 'Lundbeck' or 'the appellants'), specialising in the development and distribution of pharmaceuticals for the treatment of disorders in the central nervous system, including depression. (10)

1. Product and patents in dispute

8. Lundbeck's products include an antidepressant containing the active pharmaceutical ingredient ('API') citalopram. Lundbeck first obtained patents for that API itself as well as for alkylation and cyanation manufacturing processes. As regards the European Economic Area ('EEA'), the protection

afforded by those original patents and, where appropriate, the supplementary protection certificates, (11) expired between 1994 (for Germany) and 2003 (for Austria). In the specific case of the United Kingdom, the original patents expired in January 2002. (12)

9. Over time, Lundbeck developed other, more effective, processes for the production of citalopram, in respect of which it applied for and often obtained patents in several EEA countries as well as through the Patent Cooperation Treaty of the World Intellectual Property Organisation (WIPO) and from the European Patent Office (EPO). In particular, between 2001 and 2003, Lundbeck obtained patents for the production of citalopram by processes using amide and iodo, respectively, and for the production of citalopram by crystallisation and film distillation ('the patents in dispute'). (13)

10. Lastly, Lundbeck planned to launch a new antidepressant medicinal product, Cipralex, based on the API known as escitalopram (or S-citalopram), by the end of 2002 or the beginning of 2003. That new medicinal product was designed for the same patients as those who could be treated by Lundbeck's patented medicinal product Cipramil, based on the citalopram API. The escitalopram API was protected by patents valid until at least 2012. (14)

2. Agreements between Lundbeck and the generic manufacturers

11. In 2002, Lundbeck entered into six agreements concerning citalopram ('the agreements at issue') with four undertakings active in the production or sale of generic medicinal products ('the generic manufacturers').

12. In the first place, Lundbeck entered into a first agreement covering the territory of the United Kingdom with the English undertaking Generics UK Ltd, controlled by Merck KGaA through Merck Generics Holding GmbH (taken together, 'Merck (GUK)'), which came into effect on 24 January 2002 and expired on 1 November 2003. That agreement essentially stipulated that Merck (GUK) would deliver its stock of generic citalopram to Lundbeck and that Lundbeck would sell citalopram to Merck (GUK) for resale in the United Kingdom and make significant value transfers to Merck (GUK). In total, over the entire term of that agreement, Lundbeck transferred the equivalent of EUR 19.4 million to Merck (GUK). (15)

13. Furthermore, Lundbeck entered into a second agreement with Merck (GUK) covering the EEA, which came into effect on 22 October 2002 and expired on 22 October 2003. Under that second agreement, Lundbeck was to pay Merck (GUK) the sum of EUR 12 million, in exchange for which the latter undertook not to sell or supply pharmaceutical products containing citalopram in the territory of the EEA (with the exception of the United Kingdom) and to use all reasonable efforts to ensure that Natco Pharma Ltd, the producer of the API of its citalopram, ceased to supply citalopram and products containing citalopram in the EEA during the term of the agreement. (16)

14. In the second place, Lundbeck entered into a first agreement concerning the territory of the United Kingdom with Arrow Generics Ltd and Resolution Chemicals Ltd, both controlled by Arrow Group A/S (taken together, 'Arrow'), which came into effect on 24 January 2002 and expired on 20 October 2003. That agreement essentially stipulated that Arrow would not make, dispose of or use the citalopram that was considered by Lundbeck to infringe its intellectual property rights, in exchange for value transfers from Lundbeck in the amount of 6.8 million pounds sterling (GBP), and would deliver its stock of citalopram to Lundbeck. (17)

15. Furthermore, Lundbeck entered into a second agreement with Arrow concerning the territory of Denmark, which came into effect on 3 June 2002 and expired on 1 April 2003. Under that second agreement, Arrow agreed to cease any importation, manufacture, production, sale or other marketing of products containing the citalopram that, according to Lundbeck, infringed the latter's intellectual property rights, in exchange for a value transfer from Lundbeck of 500 000 United States dollars (USD), and Lundbeck agreed to purchase Arrow's stock of citalopram for USD 147 000. (18)

16. In the third place, Lundbeck entered into an agreement with Alpharma ApS, which later became Xellia Pharmaceuticals ApS and was controlled by Alpharma Inc., itself controlled by A.L. Industrier AS (taken together, 'Alpharma'). That agreement came into effect on 22 February 2002 and expired on 30 June 2003. It concerned all EU Member States, Norway and Switzerland, and essentially stipulated that Alpharma and its subsidiaries would cancel, cease and desist from any importation, production or sale of pharmaceutical products containing citalopram, in exchange for the transfer of USD 12 million from Lundbeck, and that Alpharma would deliver its stock of generic citalopram to Lundbeck. (19)

17. Finally, in the fourth place, Lundbeck entered into an agreement with Ranbaxy Laboratories Ltd and Ranbaxy (UK) Ltd (taken together, 'Ranbaxy'), which came into effect on 16 June 2002 and expired on 31 December 2003. It concerned the territory of the EEA and essentially stipulated that Ranbaxy would cancel, cease and desist from any manufacture or sale of citalopram, in exchange for the payment of USD 9.5 million by Lundbeck, and that Lundbeck would sell citalopram tablets to Ranbaxy with a discount of 40% on the ex-factory price for the purpose of their sale on the UK market. (20)

3. Commission decision

18. In the decision at issue, the Commission found that the purpose of the agreements at issue was to exclude the generic manufacturers from the market for the agreed period of time by means of payments made to them by Lundbeck. Accordingly, the Commission classified those agreements as restrictions of competition by object and imposed fines on Lundbeck and the other parties thereto.

19. Since, as regards Lundbeck, the Commission found that the six agreements had given rise to four separate infringements, it received four separate fines. The fine imposed on Lundbeck A/S, totalling EUR 93 766 000, of which EUR 5 306 000 jointly and severally with Lundbeck Ltd, can be broken down as follows:

– EUR 19 893 000, of which EUR 5 306 000 jointly and severally with Lundbeck Ltd, for the two agreements entered into with Merck (GUK), which were considered to have constituted a single and continuous infringement lasting from 24 January 2002 until 1 November 2003;

– EUR 12 951 000 for the two agreements entered into with Arrow, which were considered to have constituted a single and continuous infringement lasting from 24 January 2002 until 20 October 2003;

– EUR 31 968 000 for the agreement entered into with Alpharma, which was considered to be an infringement lasting from 22 February 2002 until 30 June 2003; and

– EUR 28 954 000 for the agreement entered into with Ranbaxy, which was considered to be an infringement lasting from 16 June 2002 until 31 December 2003. (21)

B. Procedure before the General Court

20. By document of 30 August 2013, Lundbeck brought an action before the General Court for the annulment of the decision at issue and, in the alternative, for the cancellation or reduction of the fines imposed on it. Before the General Court, Lundbeck was supported in its form of order by the European Federation of Pharmaceutical Industries and Associations ('EFPIA').

21. By the judgment under appeal, the General Court dismissed the action in its entirety and ordered Lundbeck to bear its own costs and to pay the Commission's costs, while EFPIA was ordered to bear its own costs.

III. Procedure before the Court of Justice and forms of order sought by the parties

22. By document of 18 November 2016, Lundbeck lodged an appeal against the judgment of the General Court, again supported in its form of order by EFPIA.

23. At the same time, the other addressees of the decision at issue also lodged appeals against the judgments of the General Court dismissing their actions against that decision, (22) and it was decided that all those appeals would be dealt with in a coordinated manner.

24. By order of the President of the Court of 13 December 2016, *Lundbeck* v *Commission*, (23) the confidential version of the decision at issue was given confidential treatment in relation to EFPIA.

25. By document of 10 March 2017, the United Kingdom of Great Britain and Northern Ireland applied for leave to intervene in the present appeal proceedings in support of the form of order sought by the Commission. By order of the President of the Court of 5 July 2017, *Lundbeck* v *Commission*, (24) the United Kingdom was granted leave to intervene and the confidential version of the decision at issue was given confidential treatment in relation to that Member State.

26. The written part of the procedure in the present case was closed on 13 November 2017, after all the written pleadings of the various parties had been lodged. Taken as a whole, those pleadings comprised almost 300 pages excluding annexes, the judgment under appeal and the decision at issue, and thus far exceeded, particularly as regards the pleadings of Lundbeck and the Commission, the length recommended in the Practice Directions to parties concerning cases brought before the Court.

27. By decision of the Court of 27 November 2018, this case was assigned to the Fourth Chamber which is to adjudicate following a joint hearing with the other five appeals brought against the judgments of the General Court dismissing the actions against the decision at issue. (25)

28. Lundbeck claims that the Court should:

– set aside the judgment under appeal in its entirety or in part;

– annul the decision at issue in so far as it concerns Lundbeck or, in the alternative, annul the fines imposed on it or, in the further alternative, substantially reduce those fines;

– order the Commission to pay the legal and other costs incurred by Lundbeck in the appeal proceedings and the proceedings before the General Court;

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

– take any other measures that the Court considers appropriate.

29. EFPIA contends that the Court should:

– allow the appeal in its entirety or in part;

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

– order the Commission to pay the costs incurred by EFPIA in the appeal proceedings and the proceedings before the General Court.

30. The Commission contends that the Court should:

– dismiss the appeal in its entirety;

– order the appellants to pay the costs.

31. The United Kingdom contends that the Court should:

– dismiss Lundbeck's appeal in its entirety.

32. The parties presented oral argument and answered the questions put to them by the Court at the joint hearing on 24 January 2019.

33. On 30 January 2020, the Court delivered its judgment in *Generics (UK) and Others*. (26) On 7 February 2020, on the basis of Article 62(1) of the Rules of Procedure of the Court, the parties to the present proceedings were given the opportunity to provide written comments on the possible impact of that judgment on the grounds of appeal raised in the instant case relating to the existence of potential competition between Lundbeck and the generic manufacturers party to the agreements at issue and the classification of those agreements as restrictions of competition by object. The answers to that question were received by the Court on 6 March 2020.

IV. Assessment

34. By their grounds of appeal, the appellants challenge the General Court's findings both as to the existence of an infringement of Article 101 TFEU (A) and as to the appropriateness of the fine imposed by the Commission (B).

A. Existence of an infringement of Article 101 TFEU (first to fourth grounds of appeal)

35. Concerning the existence of an infringement of Article 101 TFEU, the appellants submit, by their first to third grounds of appeal, that the General Court erred in law in confirming the Commission's finding that the agreements at issue amounted to restrictions of competition by object. By their fourth ground of appeal, the appellants assert that the General Court wrongly upheld the Commission's assessment that, at the time the agreements were concluded, there was a potential competitive relationship between Lundbeck and the generic manufacturers.

36. Since Article 101 TFEU applies solely to sectors open to competition, the classification of an agreement between undertakings as having the object of restricting competition presupposes that there is competition which may be restricted. (27) Accordingly, in this Opinion I will first deal with the appellants' ground of appeal relating to the existence of potential competition between Lundbeck and the generic manufacturers (1), before turning to the grounds relating to the classification of the agreements at issue as restrictions of competition by object (2).

1. Existence of potential competition between Lundbeck and the generic manufacturers (fourth ground of appeal)

37. The fourth ground of appeal is divided into several parts.

38. First, the appellants submit that the General Court erred in law by disregarding the fact that Lundbeck's patents constituted legal barriers to entry to the citalopram market, which prevented there being any competitive relationship between Lundbeck and the generic manufacturers (see (a) below).

39. Next, the appellants claim that the General Court erred in its assessment of the evidence adduced by the Commission to demonstrate the existence of potential competition between Lundbeck and those manufacturers (see (b) below).

40. Lastly, the appellants put forward arguments intended to show that the General Court was wrong to confirm the Commission's findings as to the existence of a potential competitive relationship between Lundbeck and each of the generic manufacturers concerned (see (c) below).

(a) Alleged existence of legal barriers to entry to the citalopram market arising from Lundbeck's patents

41. According to the appellants and EFPIA, the General Court erred in law by failing to acknowledge that Lundbeck's patents gave rise, on account of the presumption of validity they enjoy, to legal barriers precluding the market entry of the generic manufacturers and thus the existence of any potential competition between Lundbeck and those manufacturers. The possibility of an 'at risk' launch of a generic product on the market, which may result in an action for infringement being brought by the manufacturer of the originator medicinal product, arguing that patent rights still covering the latter preclude the market entry of the generic product, cannot, claim the appellants, be regarded as a real and concrete possibility of joining the market. Thus, where exclusive rights are involved, it is necessary to show that undertakings which may be classed as potential competitors have had the opportunity to enter the market lawfully, that is to say, without infringing any patent rights of undertakings present on the market. Therefore, by not requiring the Commission to prove that the generic manufacturers could have entered the market without infringing Lundbeck's patents, the General Court disregarded the rules relating to the burden of proof.

42. The Commission contends, as a preliminary point, that some of the patents in dispute had not yet been granted and were still at the application stage or the stage of examination by the competent authorities when a number of the agreements at issue were concluded. (28)

43. However, there is no need to examine that objection further since, in any event, the appellants' line of argument that the patents in dispute constituted insurmountable legal barriers to market entry for the generic manufacturers cannot succeed, even if those patents had already been granted when the agreements at issue were concluded.

44. Thus, in the judgment under appeal, the General Court rejected Lundbeck's arguments in that respect, finding, inter alia, that they were based on the incorrect premiss that there was no doubt that the patents in dispute were valid and had been infringed by each of the competing generic products. The General Court thus stated that, whilst patents are indeed presumed valid until they are expressly revoked or invalidated by a competent authority or court, that presumption of validity cannot be equated with a presumption of illegality of generic products validly placed on the market which the patent holder deems to be infringing the patent. Accordingly, an at risk entry is not unlawful in itself and it would on the contrary have been for Lundbeck to prove, in the event that generics entered the market, that those generics infringed one of its process patents and to defend itself against any claims of invalidity of those patents raised by the generic manufacturers. Therefore, the General Court held that the Commission did not err in finding that Lundbeck's process patents did not constitute insurmountable barriers for the generic manufacturers. (29)

45. Contrary to the appellants' arguments, those findings are not vitiated by any error of law.

46. It is indeed true that, in order to determine whether an undertaking outside a given market is a potential competitor of the undertakings established on that market, it is necessary to examine whether the relevant market has insurmountable barriers to entry (30) and whether the undertakings that may be classed as potential competitors of the undertakings established on that market have real and concrete possibilities of competing with the latter. (31)

47. However, as the Court recently found in its judgment in *Generics (UK) and Others*, in a situation such as the present one, involving an assessment of the potential competitive relationship between, on the one hand, a manufacturer of originator medicinal products holding a process patent for the production of an active substance in the public domain, and, on the other, manufacturers of generic medicinal products who are taking steps to enter the market of the medicinal product containing that active substance, the existence of a patent protecting the manufacturing process of that substance cannot, as such, be regarded as an insurmountable barrier.

48. Thus, the existence of such a process patent does not mean that a manufacturer of generic medicinal products who has in fact a firm intention and an inherent ability to enter the market, and who, by the steps taken, shows a readiness to challenge the validity of that patent and to take the risk, upon entering the market, of being subject to infringement proceedings brought by the patent holder, cannot be characterised as a 'potential competitor' of the manufacturer of the originator medicinal product concerned. (32)

49. The existence of a patent for a medicinal product does not constitute an insurmountable barrier to market entry for a manufacturer of a generic version of that product because, among other things, the presumption of validity of patents is merely the automatic consequence of the registration of a patent and its subsequent issue to its holder, and therefore sheds no light on the outcome of any dispute relating to the validity of that patent. (33) Accordingly, the appellants are wrong to claim that the possibility of the future invalidation of a patent is irrelevant for the purpose of establishing a potential competitive relationship between the holder and other economic operators.

50. It is indeed true that, as the appellants point out, when granted by a public authority, an intellectual property right is normally assumed to be valid and an undertaking's ownership of that right is assumed to be lawful. (34) Consequently, patents are assumed valid until they are expressly revoked or invalidated by a competent authority or court. Nevertheless, such a presumption of validity cannot, as the General Court correctly held in the judgment under appeal, be equated with a presumption of illegality of generic products validly placed on the market which the patent holder deems to be infringing that patent. (35)

51. The uncertainty as to the validity of patents protecting an originator medicinal product and as to whether generic versions of that product infringe those patents is, on the contrary, a fundamental characteristic of competitive relationships in the pharmaceutical sector. (36) Disputes and legal proceedings in that context thus constitute evidence of the existence of a competitive relationship between the operators concerned. (37)

52. Thus, as the Court made clear in the case-law to which the General Court rightly referred in the judgment under appeal, (38) the purpose of a patent is indeed to ensure that the proprietor has the exclusive right to use an invention with a view to manufacturing products and putting them into circulation for the first time, as well as the right to oppose infringements. (39) However, that purpose cannot be interpreted as also affording protection against actions brought in order to challenge the patent's validity, in view of the fact that it is in the public interest to eliminate obstacles to economic activity which may arise where a patent was granted in error. (40)

53. Therefore, it is an integral part of patent law that, despite the presumption that patents are valid, there can be certainty as to that validity and as to whether competing products infringe a patent only once those matters have been examined by the competent authorities and courts.

54. Against that background, disputes and legal proceedings between manufacturers of originator medicinal products and manufacturers of generic versions of those products often form part of the preparations for the market entry of generics. Moreover, since, in order to obtain a marketing authorisation ('MA') for a generic medicinal product, it is not necessary to show that that product does not infringe any patent rights of the manufacturer of the originator medicinal product, (41) uncertainty as to the validity of the patent and as to whether the generic medicinal product infringes it may persist even after the market entry of such a product.

55. Consequently, it cannot be argued that an at risk entry of a generic product to the market, which may result in an action for infringement being brought by the holder of a patent for the originator medicinal product, does not constitute a real and concrete possibility for a generic manufacturer to penetrate the market where patent rights over the originator medicinal product still exist.

56. As the General Court rightly pointed out in the judgment under appeal, (42) that is all the more true in a situation such as that of the present case, where the patents in dispute are not compound patents protecting the actual API of the originator medicinal product, but rather process patents protecting certain

methods of manufacturing that API. Consequently, unlike a compound patent, those process patents — irrespective of whether or not they are valid — do not prevent the generic manufacturers from entering the market with the relevant API manufactured under other processes. In other words and conversely, in a situation where the patent for a medicinal product's API has expired and an originator undertaking holds only process patents, the entry of generic versions of the medicinal product in question infringes solely the patent rights of that originator if it is established that the process patents at issue are both valid and infringed by each of the potential entrants. (43)

57. In those circumstances, it cannot be argued, as the appellants suggest, that in order to demonstrate the existence of a competitive relationship between the holder of a patent for a medicinal product and a manufacturer of a generic version of that product, the Commission is 'required to affirmatively prove' that the generic product in question does not infringe the patent concerned, that is to say, in the present case, that the processes used by the generic manufacturers to produce citalopram did not infringe the patents in dispute held by Lundbeck.

58. It is not for the Commission, by assessing the strength of the patents concerned or whether generic products infringe them, to make predictions concerning the outcome of disputes between patent holders and generic manufacturers, in order to assess the competitive relationships between those operators for the purpose of applying competition law. As the General Court summarised, in essence, in paragraph 159 of the judgment under appeal, requiring the Commission to prove that the generic manufacturers would certainly or very probably have been successful in patent proceedings with Lundbeck and would certainly or very probably have entered the market with their products would, moreover, be to confuse actual and potential competition and to ignore the fact that Article 101 TFEU also precisely protects the latter. (44)

59. Admittedly, a competition authority should not disregard any question relating to patent law which is capable of influencing the finding that such a competitive relationship exists, since any patents protecting an originator medicinal product or one of its manufacturing processes undeniably form part of the economic and legal context of the competitive relationships between the holders of those patents and the manufacturers of generic medicinal products. However, the assessment of the rights conferred by a patent, to be carried out by the competition authority, must not consist of an examination of the strength of the patent or of the likelihood of a dispute between the patent holder and a manufacturer of generic medicinal products being brought to an end with a finding that the patent is valid and has been infringed. That assessment must rather have regard to the question of whether, notwithstanding the existence of that patent, the manufacturer of generic medicinal products has real and concrete possibilities of entering the market at the relevant time. (45)

60. To that effect, account must be taken not only of the fact that a process patent does not prevent the market entry of products manufactured under other processes, but also, inter alia, of the following: that the uncertainty as to the validity of patents covering medicinal products is a fundamental characteristic of the pharmaceutical sector; that the presumption of validity of a patent for an originator medicinal product does not amount to a presumption that a generic version of that product properly placed on the market is illegal; that a patent does not guarantee protection against actions seeking to contest its validity; and that such actions, and, in particular, the 'at risk' launch of a generic medicinal product, and the consequent court proceedings, commonly take place in the period before or immediately after the market entry of such a generic medicinal product. (46)

61. It follows that continued uncertainty as to the lawfulness of the marketing of a generic medicinal product under patent law in no way precludes a finding that the manufacturer of that generic product has real and concrete possibilities of entering the market in question and that there is, therefore, a potential competitive relationship between that manufacturer and the holder of a patent for the originator medicinal product for the purpose of the application of Article 101 TFEU.

62. Consequently, the appellants cannot argue that the existence of patents protecting a particular medicinal product constitutes a legal barrier excluding all competition in the same way as exclusive rights

recognised as constituting such barriers in previous cases, (47) as, moreover, the General Court correctly explained in the judgment under appeal, (48) contrary to the appellants' assertions.

63. Similarly, paragraph 29 of the Commission's Guidelines on the application of Article 101 of the TFEU to technology transfer agreements, (49) relied on by the appellants, indeed states that the parties to an agreement are not considered to be competitors when a technology right cannot be exploited without infringing another valid technology right. However, that same paragraph states that, in practice, there will be cases where there is no certainty whether a particular technology right is valid and infringed, which is precisely the case with patents such as those at issue in this case.

64. It follows from the foregoing that the General Court did not err in finding that the patents in dispute did not constitute insurmountable barriers to the entry of the generic manufacturers to the citalopram market and that, in order to demonstrate the existence of a potential competitive relationship between Lundbeck and those manufacturers, the Commission was not required to show that the latter were able to enter the market without infringing any of Lundbeck's patent rights.

65. The first part of the fourth ground of appeal must therefore be rejected.

(b) Alleged errors made by the General Court in its assessment of the evidence adduced by the Commission to demonstrate the existence of potential competition between Lundbeck and the generic manufacturers

66. By the second and third parts of their fourth ground of appeal, which should be considered together, the appellants claim that the General Court erred in its assessment of the evidence purporting to show the existence of potential competition between Lundbeck and the generic manufacturers when the agreements at issue were concluded.

67. The Commission contends that, by that line of argument, the appellants seek to call into question the General Court's findings of fact and to have the Court of Justice re-examine the evidence submitted to the General Court, which is inadmissible in the context of an appeal.

68. That objection must, however, be qualified.

69. Thus, it is indeed true that the appellants put forward a number of arguments relating to the General Court's appraisal of the facts that are inadmissible at the appeal stage, save where the clear sense of the evidence is distorted, which in this case is neither alleged nor apparent. (50)

70. Nevertheless, it must be noted that the nub of the appellants' arguments concerns the methodology applied by the Commission and the General Court to arrive at the finding that there was potential competition between Lundbeck and the generic manufacturers when the agreements at issue were concluded, which is moreover illustrated by the Commission's own responses to the appellants' claims. Accordingly, these are points of law subject to review by the Court on appeal.

71. The appellants thus assert that the General Court was wrong to endorse the Commission's approach of relying primarily on evidence of Lundbeck's subjective assessment of the strength of its patents in order to conclude that there was potential competition between Lundbeck and the generic manufacturers, thereby failing to take account of a great deal of objective evidence capable of demonstrating that no such potential competition existed.

72. In so doing, the General Court arbitrarily and citing contradictory reasons refused to take account of evidence subsequent to the conclusion of the agreements at issue when to do so would have been advantageous to the appellants, while it did not hesitate to rely on such subsequent evidence to draw conclusions to the appellants' disadvantage.

73. That argument cannot, however, succeed.

74. The appellants' claims are based, first, on a biased and misleading interpretation of the judgment under appeal.

75. As the Commission rightly points out, the General Court expressly stated, in paragraph 142 of the judgment under appeal, that the appellants were wrong to submit that the Commission relied 'almost exclusively' on subjective assessments by Lundbeck of the strength of its patents in order to establish the existence of potential competition between Lundbeck and the generic manufacturers.

76. The General Court further found, again in paragraph 142 of the judgment under appeal, that the Commission had carried out a careful examination, as regards each of the generic undertakings concerned, of the real concrete possibilities they had of entering the market, relying on objective evidence such as, in particular, the investments already made, the steps taken in order to obtain an MA and the supply contracts concluded with their API suppliers. In addition, in paragraph 144 of the judgment under appeal, the General Court also relied on other objective evidence, such as the very existence of the agreements at issue and the payments made by Lundbeck to the generic manufacturers, in order to conclude that the Commission had demonstrated to the requisite legal standard that there was potential competition between those operators.

77. Such an approach is consistent with the criteria laid down by the Court for the purpose of assessing potential competition between the holder of a patent for a medicinal product and a manufacturer of a generic version of that product.

78. In order to decide whether a potential competitive relationship exists between such operators, it is necessary to determine whether, at the time the agreements at issue were concluded, the generic manufacturer had taken sufficient preparatory steps, in administrative, judicial and commercial terms, to enable it to enter the market concerned within such a period of time as would impose competitive pressure on the manufacturer of originator medicinal products and thus establish its firm intention and inherent ability to enter that market notwithstanding the existence of process patents still held by that manufacturer. (51)

79. Moreover, in order to establish the existence of potential competition between a generic manufacturer and an originator undertaking, account must be taken of the latter's perception of the risk posed by the former to its commercial interests, as evidenced in particular by the very conclusion of an agreement between those operators and the readiness of the originator undertaking to make value transfers to the generic manufacturer in return for postponing its market entry. (52)

80. Secondly, it follows from the foregoing that, in contrast to what the appellants appear to claim, the General Court's approach of relying, among a body of evidence, also on evidence of Lundbeck's perception of the competitive pressure exerted by the generic manufacturers, in order to find that there was a potential competitive relationship, does not entail any methodological error. On the contrary, the perception of the established operator is a factor that is relevant to the assessment of the existence of a competitive relationship between that party and an undertaking outside the market. (53)

81. Accordingly, the General Court did not err when it took into account, among other things, particularly in paragraph 145 of the judgment under appeal which the appellants call into question, the fact that Lundbeck doubted the validity of its patents in order to conclude that the Commission had established to the requisite legal standard that there was potential competition between Lundbeck and the generic manufacturers.

82. Nevertheless, the appellants submit, thirdly, that the General Court erred in finding, in the light of the documents it relied on, that Lundbeck doubted the validity of its patents, when those documents had been drawn up after the conclusion of the agreements at issue. According to the appellants, the General Court thereby incorrectly, inconsistently and arbitrarily admitted evidence subsequent to the conclusion of those agreements to the disadvantage of the appellants, while it refused to take account of such subsequent evidence when adduced to the appellants' advantage.

83. That argument is, however, also unfounded.

84. Thus, it is true that the General Court cannot endorse a finding of infringement of EU competition law where it is in possession of evidence capable of invalidating such a finding. (54) Nonetheless, it is also settled case-law that the prevailing principle under EU law is that evidence may be freely adduced and that the only relevant criterion for the purpose of assessing the evidence adduced relates to its credibility. (55) According to the generally applicable rules on evidence, the credibility and, therefore, the probative value of a document depend on its origin, the circumstances in which it came into being, the person to whom it is addressed and the soundness and reliable nature of its contents. (56)

85. In the present case, the assessment of the evidence by the General Court, challenged by the appellants, is in line with those principles.

86. Thus, the General Court correctly stated, in paragraphs 139 and 141 of the judgment under appeal, that the Commission was right to rely, in order to evaluate the competitive situation between the parties to the agreements at issue when those agreements were concluded, on documents reflecting those parties' perception of the strength of the patents in dispute at that time. It is solely on the basis of the information available to them at the time and their perception of the market at that time that they decided to adopt a particular course of conduct and concluded the agreements at issue. It is therefore correct, as the General Court also stated in paragraph 141 of the judgment under appeal, that evidence subsequent to the conclusion of the agreements at issue may be taken into account where it is capable of clarifying the parties' positions at the relevant time.

87. Consequently, contrary to the appellants' claims, the General Court did not err or reverse the burden of proof when it relied, in paragraph 254 of the judgment under appeal, on evidence dating from the period after the conclusion of the agreements at issue in order to find that Lundbeck had doubts about the validity of the patents in dispute, stating that Lundbeck had not provided any evidence capable of explaining how, hitherto, its assessment of that question would have been different.

88. The documents whose consideration by the General Court is called into question by the appellants were internal documents of Lundbeck. (57) They were not, therefore, documents drawn up after the conclusion of the agreements at issue for the purpose of Lundbeck's defence in the proceeding before the Commission, which would have been a factor liable to undermine their credibility. (58) Accordingly, the General Court was able to find, without erring or reversing the burden of proof, that in the absence of evidence showing that Lundbeck had reasons to alter radically its position in that regard after the conclusion of the agreements at issue, it was credible that those documents also reflected Lundbeck's perception of the strength of its patents at the time those agreements were concluded.

89. Furthermore, the appellants are also wrong to submit that the General Court erred where it refused to take into account, in paragraphs 136 and 143 to 146 of the judgment under appeal, the evidence adduced by Lundbeck to show that the generic manufacturers had infringed its patents, that it had been granted injunctions or other forms of interim relief in infringement proceedings, or that the EPO had confirmed the crystallisation patent in all relevant aspects in 2009.

90. Contrary to the appellants' assertion, the General Court did not refuse to take that evidence into account solely because it was subsequent to the conclusion of the agreements at issue. The real reason for that refusal was instead that the evidence was simply not relevant for the purpose of assessing the competitive relationships between Lundbeck and the generic manufacturers at the time those agreements were concluded, even though it concerned objective facts and not subjective statements made *in tempore suspecto*. Thus, as the General Court rightly found, that evidence did not alter the fact that, at the time the agreements were concluded, Lundbeck perceived the generic manufacturers as a threat, all of those operators doubted the validity of the crystallisation patent, and it could not be ruled out that a national court might declare the latter invalid.

91. Contrary to the view taken by the appellants, irrespective of whether it is the case here, the fact that the perception of a given state of affairs by an operator when an agreement is concluded subsequently proves to be unfounded does not preclude that perception from being taken into account for the purpose of assessing potential competition at the relevant time. The appellants' notion that operators might 'wrongly' consider themselves 'subjectively' to be potential competitors at a given time, when it might subsequently transpire that, 'objectively', they were in fact not potential competitors at that time, is unfounded. That notion fails to take account of the fact that operators necessarily act, at a given time, on the basis of their perception of affairs as they stand at that time and that those actions in turn shape the state of affairs by contributing to the existence or the absence of potential competition. Therefore, if, based on a body of evidence, it can be concluded that a potential competitive relationship exists at a given time, a subsequent event or fact cannot retrospectively invalidate the existence of such potential competition at the relevant time.

92. Moreover, and in any event, in order to conclude that there was potential competition in this case, the General Court relied on a number of factors, not only on the possibility of the crystallisation patent being found to be invalid or the perception of the parties in that regard. Likewise, it is not necessary to determine whether the General Court was right to find, in paragraph 146 of the judgment under appeal, that, at the time the agreements at issue were concluded, no interim measure had been obtained by Lundbeck, which is disputed by the appellants. In any event, the existence of such interim measures is not such as to invalidate the finding that there was potential competition between an originator undertaking and generic manufacturers against which the former had obtained such measures. (59)

93. It follows from the foregoing considerations that the General Court did not commit any methodological errors in its assessment of the evidence adduced by the Commission to demonstrate the existence of potential competition between Lundbeck and the generic manufacturers at the time the agreements at issue were concluded.

94. The second and third parts of the fourth ground of appeal must therefore also be rejected.

(c) The appellants' arguments claiming that there was no potential competitive relationship between Lundbeck and each of the generic manufacturers concerned

95. By the fourth to seventh parts of their fourth ground of appeal, the appellants submit that the General Court erred in upholding, in paragraphs 207 to 330 of the judgment under appeal, the Commission's findings as to the existence of a potential competitive relationship between Lundbeck and each of the generic manufacturers in question in each of the territories concerned by the agreements at issue.

96. The Commission again contends that this line of argument is inadmissible because it seeks to call into question the General Court's findings of fact and to have the Court of Justice re-examine the evidence submitted to the General Court. However, although the appellants put forward matters of a factual nature which fall to the General Court alone to examine, it is apparent from their arguments that they also take issue with a number of methodological errors allegedly made by the General Court in its consideration of the existence of potential competition between Lundbeck and each of the generic manufacturers, which is permitted at the appeal stage.

97. Nevertheless, the appellants' arguments cannot succeed on the merits since they largely overlap with the methodological criticisms already refuted in my examination of the previous parts of this ground of appeal and, as to the remainder, are also unfounded.

98. Thus, the appellants claim, first, that the General Court was wrong to accept that there was potential competition between Lundbeck and Merck (GUK) in the United Kingdom and throughout the EEA, between Lundbeck and Arrow in the United Kingdom and Denmark, between Lundbeck and Alpharma in the EEA, and between Lundbeck and Ranbaxy in the EEA, without requiring the Commission to prove that those generic manufacturers could have entered the market with non-infringing citalopram, that is to

say, citalopram manufactured using processes other than those protected by the patents in dispute held by Lundbeck. Similarly, the appellants restate the view that it would be wrong, due to the presumption of validity enjoyed by patents, to regard the possibility of challenging that validity as an expression of the existence of potential competition.

99. However, as stated above in my examination of the first part of this ground of appeal, in order to demonstrate the existence of a competitive relationship between the holder of a patent for a medicinal product and a manufacturer of a generic version of that product, the Commission is not required to prove that the generic version does not infringe the patent concerned or that the patent would have been found to be invalid in legal proceedings, and the 'at risk' entry of a generic product to the market as well as a challenge to the validity of a patent may, on the contrary, be regarded as real and concrete possibilities of competing with the patent holder. (60)

100. Secondly, the appellants submit that the General Court was wrong to find that Merck (GUK) and Arrow were competitors of Lundbeck on the basis of subjective evidence and disregarding subsequent objective evidence. In so far as those arguments are not an attempt to have the Court of Justice re-examine factual evidence previously considered by the General Court but are rather a methodological critique of the General Court's assessment of those facts, they have already been rejected in the examination of the second and third parts of this ground of appeal above. (61)

101. Thirdly and lastly, the appellants state that the General Court was wrong to uphold the Commission's findings as to the existence of potential competition between Lundbeck and the generic manufacturers when, in some of the countries concerned by the agreements at issue, those manufacturers had applied for or obtained MAs for their products only during the term of those agreements or after their expiry.

102. In that regard, it should be noted that the General Court conducted a detailed examination, in particular in paragraphs 168 to 182 of the judgment under appeal, of whether the fact that a generic manufacturer does not yet have an MA for the market of a certain country precludes the existence of potential competition between that manufacturer and the holder of a patent for the originator medicinal product already on sale on the relevant geographic market. In addition, in those paragraphs, the General Court analysed the situation of each of the generic manufacturers party to the agreements at issue in terms of MAs for the geographic markets concerned by those agreements.

103. The General Court thus found, first of all, that the fact that a generic manufacturer does not yet have an MA for its product in a given State does not preclude the existence of potential competition between that manufacturer and an originator undertaking already active in the relevant geographic area, since potential competition includes inter alia the activities of generic manufacturers seeking to obtain MAs as well as all the administrative and commercial steps required in order to prepare for entry to the market. (62) As the General Court also stated, although the success of the procedure to obtain an MA is indispensable in order for effective competition to exist, the path to obtaining such an MA, when it is taken by an undertaking which has for a long time been seriously preparing its market entry, constitutes potential competition. (63)

104. Similarly, in paragraphs 163 and 232 of the judgment under appeal, the General Court noted that the Commission does not need to demonstrate with certainty that the entry of the generic manufacturers to the market would have taken place in each of the countries concerned by the agreements at issue before the expiry of those agreements in order to be able to establish the existence of potential competition, since potential competition does not require the demonstration of certain market entry, but merely the existence of real and concrete possibilities in that respect.

105. The appellants do not put forward any evidence to contradict those considerations, which, moreover, are not vitiated by any error of law.

106. A refusal to recognise the existence of a potential competitive relationship between the holder of a patent for a medicinal product and the manufacturer of a generic version of that product, which, moreover,

has been found to have a firm intention and an inherent ability to enter the market, simply because that manufacturer does not yet have an MA, would amount to precluding any potential competition and thereby preclude competition law from being applied during the preparatory stage of the market entry of generic medicinal products, which includes the steps taken to obtain an MA. Such a position would run completely counter to the effectiveness of Article 101 TFEU, since it would mean that the preparations of future market entrants could be halted or delayed by means of exclusion agreements, so that the market entry of such operators and, therefore, actual competition could never materialise.

107. Next, the General Court found that, in the present case, not only had the generic manufacturers been seriously preparing their market entry for a long time, but they also already had MAs or had taken steps to obtain them in the short or medium term. Against that background, the General Court specifically examined the individual situation of the generic manufacturers concerned and concluded that each of them had real and concrete possibilities of obtaining MAs and thus entering the citalopram market in several EEA countries, particularly by means of the mutual recognition procedure laid down in Directive 2001/83, (64) within a sufficiently short period to exert competitive pressure on Lundbeck. (65)

108. The appellants do not dispute the facts on which the General Court relied to reach that conclusion or claim that those facts were distorted; they merely assert that, in some of the countries concerned by the agreements at issue, the generic manufacturers applied for or obtained MAs for their products only during the term of those agreements or after their expiry.

109. Following that same line of argument, the appellants submit, in their answer to my question concerning the impact of the Court's judgment in *Generics (UK) and Others* (66) on these proceedings, (67) that the test established by the Court in that judgment to determine whether potential competition exists between the holder of a patent for a medicinal product and generic manufacturers of that product is not satisfied here.

110. However, as has just been found, the lack of an MA is not capable of invalidating the finding that there was potential competition between Lundbeck and the generic manufacturers. This holds all the more because, as the Commission rightly pointed out at the hearing in the present case, it is impossible to ascertain whether or not it was precisely the agreements at issue themselves that dissuaded those manufacturers from expediting the steps required to obtain an MA for their products in the States concerned by those agreements.

111. Contrary to the appellants' assertions, that is also consistent with the findings made by the Court in paragraphs 43 and 44 of *Generics (UK) and Others*. (68) In those paragraphs, the Court simply stated that, in order to assess whether the patent holder and a manufacturer of generic medicinal products are potential competitors of each other in circumstances similar to those in this case, it is necessary to determine whether that manufacturer had, at the relevant time, taken sufficient preparatory steps to enable it to enter the market concerned within such a period of time as would impose competitive pressure on the patent holder. Those steps *may* include, inter alia, measures taken by the manufacturer to put itself in a position to have, within that period, the required MAs.

112. However, as I have just noted, the appellants do not call into question the findings of fact relied on by the General Court to conclude that the generic manufacturers had real and concrete possibilities of obtaining MAs and thus entering the citalopram market in several EEA countries within a sufficiently short period to exert competitive pressure on Lundbeck.

113. In those circumstances, the fourth to seventh parts of the fourth ground of appeal must also be rejected, as must that ground of appeal in its entirety.

2. Classification of the agreements between Lundbeck and the generic manufacturers as restrictions of competition by object (first to third grounds of appeal)

114. By their first three grounds of appeal, the appellants claim that the General Court erred in classifying the agreements at issue as restrictions of competition by object.

115. First of all, in their first ground of appeal, the appellants submit that the General Court was wrong to uphold the Commission's assessment that those agreements would be restrictive of competition by object even if the restrictions provided for fell within the scope of the patents in dispute, that is to say, even assuming that the agreements prevented only the market entry of generic citalopram deemed potentially to infringe those patents by the parties to the agreements and not that of every type of generic citalopram. (69)

116. Next, in their second ground of appeal, the appellants argue that the General Court erred in finding that five of the six agreements at issue went beyond the scope of the patents in dispute, that is to say, they prohibited the generic manufacturers from selling all types of generic citalopram, not only citalopram manufactured using the processes protected by the patents in dispute.

117. Finally, by their third ground of appeal, the appellants state that even if the Court of Justice were to find that some of the agreements at issue went beyond the scope of the patents in dispute by prohibiting the sale of all generic citalopram, the General Court was nevertheless wrong to conclude that those agreements constituted restrictions of competition by object.

(a) Classification of agreements not exceeding the scope of a patent as restrictions of competition by object (first ground of appeal)

118. According to the appellants, the General Court erred in law in holding that the agreements at issue were restrictive of competition by their very object even assuming that the restrictions they imposed on the generic manufacturers did not go beyond the scope of the patents in dispute. Thus, the appellants maintain that an agreement imposing restrictions comparable to those that the patent holder could have obtained through court rulings cannot, by its very nature, be regarded as harmful to competition. Such an agreement merely reflects the patent holder's prerogative to keep infringing products out of the market.

119. A patent settlement agreement cannot, a fortiori, constitute a restriction of competition by object since the settlement of patent litigation is a legitimate and common means of averting disputes.

120. Lastly, the fact that the patent holder has made a significant value transfer to the generic manufacturer that signed the agreement in question cannot in that context, contrary to the General Court's findings, be relevant for the purpose of classifying an agreement as a restriction of competition by object.

121. The General Court rejected that line of argument in the judgment under appeal, explaining that there may indeed be legitimate patent dispute settlement agreements, even those providing for payments from the patent holder to a generic manufacturer. However, according to the General Court, where such a payment is combined with an exclusion of competitors from the market or a limitation of the incentives to seek market entry, it is possible to consider that that limitation does not arise exclusively from the parties' assessments of the strength of the patent but rather was obtained by means of that payment and therefore constitutes a buying-off of competition.

122. The General Court further recalled that, under Article 101 TFEU, each economic operator must determine independently the policy it intends to follow on the market. Accordingly, the General Court endorsed the Commission's assessment that patent dispute settlement agreements are caught by the prohibition laid down in that provision where they contain significant reverse payments that reduce or eliminate any incentive for the generic manufacturers to enter the market for a certain period, without, however, resolving the underlying patent dispute. In such cases, the value transfer replaces the autonomous assessment, by the parties, of the strength of the originator undertaking's patents and the assessment of their chances of succeeding in the event of litigation.

123. Consequently, the General Court held that, by concluding the agreements at issue, the appellants had exchanged the uncertainty as to the outcome of such litigation for the certainty that the generic manufacturers would not enter the market, in return for significant reverse payments, thus eliminating all competition, even potential competition, on the market, during the term of those agreements. (70)

124. The General Court therefore found that the 'scope of the patent test', according to which contractual restrictions falling within the patent holder's temporal, territorial and material rights do not infringe competition law, could not be upheld. In the General Court's view, that test leads to a presumption that a generic medicinal product infringes the originator undertaking's patent, when the question whether the generic medicinal product infringes any patents is an unresolved issue. Furthermore, according to the General Court, it is based on the premiss that any patent invoked in the context of a settlement agreement will be held valid if its validity is challenged, although there is no basis in law or in practice for that outcome.

125. Thus, according to the General Court, the fact that some restrictions contained in the agreements at issue were regarded by the Commission as potentially falling within the scope of Lundbeck's patents meant only that the appellants could have obtained comparable restrictions through court rulings enforcing their patents, assuming that they succeeded in actions brought before the competent national courts. Therefore, even if the agreements at issue also contained restrictions potentially falling within the scope of the appellants' patents, those agreements went beyond the specific subject matter of their intellectual property rights, which indeed included the right to oppose infringements, but not the right to conclude agreements by which actual or potential competitors were paid not to enter the market. (71)

126. Contrary to the appellants' arguments, those considerations are not vitiated by any error of law.

127. As the Court explained in its judgment in *Generics (UK) and Others*, (72) agreements whereby a generic manufacturer recognises the validity of a patent and gives an undertaking, in return for a value transfer from the patent holder, not to challenge it and not to enter the market, are liable to restrict competition. This is because challenging the validity of patents, particularly by means of an 'at risk' market entry, is part of normal competition in sectors where exclusive rights to technologies exist.

128. Thus, it is indeed possible for a generic manufacturer to decide independently not to enter the market and to conclude a patent dispute settlement agreement in that context. However, Article 101 TFEU requires operators to determine their conduct on the market independently and prohibits them from knowingly substituting practical cooperation between them for the risks of competition. Accordingly, a patent dispute settlement agreement is akin to a restriction of competition by object if the value transfer from the patent holder to the generic manufacturer has no explanation other than the common commercial interest of the parties not to engage in competition on the merits.

129. If the sole consideration for that transfer is the generic manufacturer's undertaking not to enter the market and challenge the patent, this indicates, in the absence of any other plausible explanation, that it is not its perception of the patent's strength but the prospect of the value transfer that prompted it to refrain from entering the market and challenging the patent.

130. Consequently, it cannot be maintained that entering into such an agreement falls within the exercise, by the patent holder, of its prerogatives stemming from the object of the patent, or that the conclusion of that agreement represents, on the part of the manufacturers of generic medicinal products, no more than their recognition of the patent rights, presumed to be valid, of the holder of that patent. Since the presumption of validity of a patent sheds no light on the outcome of any dispute relating to that validity, an agreement whereby the parties eliminate uncertainty in that regard by means of a value transfer to the generic manufacturer is akin to eliminating potential competition which would have existed were it not for that agreement. (73)

131. None of the arguments put forward by the appellants in these proceedings is capable of demonstrating that the General Court was wrong to confirm the Commission's assessment that, in the present case, the

agreements at issue constituted such restrictions of competition designed to secure the generic manufacturers' undertaking not to compete during the agreed period in return for a payment from Lundbeck, the sole consideration for which was that undertaking.

(1) Asymmetry of risks between Lundbeck and the generic manufacturers

132. First, the Court has indeed held that, in order to conclude that an agreement in settlement of a patent dispute between the patent holder and a generic manufacturer, involving a value transfer from the former to the latter, constitutes a restriction of competition by object, it must be apparent from the analysis of the agreement that that value transfer has no explanation other than the generic manufacturer's undertaking not to compete with its product during the agreed period. It must therefore be apparent that the transfer is not justified in the light of legitimate objectives of the parties to the agreement, such as compensation for the costs associated with the dispute, the actual supply of goods or services, or the discharge of financial undertakings given by the patent holder. Moreover, according to the Court, if that is the case, it is still necessary to determine whether the value transfer to the generic manufacturer was sufficiently large actually to act as an incentive to it to refrain from entering the market concerned. (74)

133. However, the appellants do not adduce any evidence that might demonstrate that, in the present case, the value transfers from Lundbeck to the generic manufacturers were made in exchange for any consideration from the latter aside from their undertaking not to enter the market. Similarly, the appellants do not put forward any evidence that might cast doubt on the General Court's finding that, in this instance, the amounts of the reverse payments provided for in the agreements at issue were sufficiently high to allow the generic manufacturers to accept the limitations on their autonomy and to reduce their incentives to enter the market. Thus, the General Court held that it was apparent from the material in the file that those manufacturers would not have agreed to stay out of the market unilaterally, after having taken significant steps and having made significant investments, in the absence of the payments to them from Lundbeck. (75)

134. Instead of adducing even minimal concrete evidence that might provide an alternative explanation for those payments to the explanation accepted by the Commission and the General Court, the appellants simply submit that those payments are ascribable to the asymmetry of risks between Lundbeck and the generic manufacturers. Thus, if the generic manufacturers had entered the market in breach of Lundbeck's patents, the damages that Lundbeck could have obtained following successful legal proceedings would never have been sufficient to compensate for the losses sustained, which would explain its readiness to make the payments at issue.

135. However, as the General Court rightly pointed out in paragraphs 379 to 387 of the judgment under appeal, the fact that the conclusion of an agreement is a rational and cost-effective course of action in economic and commercial terms for the parties does not mean that such an agreement falls outside the scope of Article 101 TFEU. Similarly, it is for public authorities and not private undertakings to ensure compliance with statutory requirements. (76) It is therefore not for such undertakings to redress alleged legislative inadequacies by means of anticompetitive agreements and thus take the law into their own hands. (77) Accordingly, 'asymmetry of risks' such as that claimed by the appellants, like possible shortcomings in national patent law, cannot, even if proven, justify agreements whereby an economic operator pays its competitors to stay out of the market.

(2) The 'counterfactual scenario'

136. Secondly, the appellants claim that the General Court erred in law by refusing, in paragraphs 472 and 473 of the judgment under appeal, to examine the 'counterfactual scenario', that is to say, the situation that would have arisen had it not been for the agreements at issue. According to the appellants, such an examination would have shown that the generic manufacturers refrained from entering the market not on account of the existence of those agreements, but quite simply on account of the existence of Lundbeck's patents.

137. The appellants further insist on this point in their answer to my question concerning the impact of the judgment of the Court in *Generics (UK) and Others* (78) on these proceedings, (79) maintaining that, in that judgment, the Court acknowledged the importance of the counterfactual analysis and of taking into account the pro-competitive effects of the agreements under consideration, which would not have existed in the absence of those agreements, when applying Article 101 TFEU.

138. However, it should be noted, first of all, that in paragraph 37 of the judgment in *Generics (UK) and Others*, relied on by the appellants, the Court merely stated that, for the purpose of analysing the existence of a potential competitive relationship between economic operators, it is necessary to determine whether, in the absence of the agreement, there would have existed real and concrete possibilities for an undertaking outside the market to compete with the undertaking already established there.

139. Irrespective of whether such an analysis may bear similarities to a 'counterfactual' analysis of what would have occurred in the absence of an agreement and whether it is necessary to conduct such a counterfactual analysis in cases involving agreements constituting restrictions of competition by object, suffice it to note that, in the judgment under appeal, the General Court carried out a detailed examination of whether the generic manufacturers had real and concrete possibilities of entering the market at the time the agreements at issue were entered into, so that it can be concluded that such possibilities were eliminated by those agreements. (80)

140. Moreover, it is incorrect to state, as the appellants do, that a counterfactual analysis would have shown that the generic manufacturers refrained from entering the market not as a result of the agreements at issue, but as a result of the existence of Lundbeck's patents which prevented entry to the market with infringing products. That argument disregards the fact that, at the time the agreements at issue were concluded, there was uncertainty as to the validity of the patents in dispute and the infringing nature of the generic manufacturers' products. However, as the Court held in *Generics (UK) and Others*, (81) it is precisely that uncertainty which contributes, for as long as it lasts, to the existence of a situation of at least potential competition between the holder of a patent for a medicinal product and a manufacturer wishing to enter the market with a generic version of that product.

141. Accordingly, if it is established that an agreement seeks to eliminate that uncertainty, it may be concluded that it constitutes a restriction of competition by object, since it substitutes a concerted situation that is the result of practical cooperation between the parties for a situation in which the parties independently manage the risks and opportunities arising from that uncertainty. (82) It was precisely by means of an analysis of that point that the General Court reached the conclusion that the agreements at issue in the present case constituted restrictions of competition by object. (83)

142. As regards, lastly, the taking into account of any pro-competitive effects of an agreement, it is indeed true that the Court held, in paragraph 103 of the judgment in *Generics (UK) and Others*, (84) relied on by the appellants, that such effects must, as elements of the context of that agreement, be duly taken into account for the purpose of its characterisation as a restriction of competition by object, in so far as they are capable of calling into question the overall assessment of whether the concerted practice concerned revealed a sufficient degree of harm to competition and, consequently, of whether it should be characterised as a restriction of competition by object.

143. However, in the instant case, the appellants do not claim, in their pleadings in the present appeal proceedings, that the agreements at issue had pro-competitive effects which would have been capable of calling into question the General Court's analysis regarding the characterisation of those agreements as restrictions of competition by object.

(3) Absence of no-challenge clauses in the agreements at issue

144. Thirdly, the appellants submit, in their answer to my question concerning the impact of the judgment in *Generics (UK) and Others* on these proceedings, (85) that the Court's analysis in that judgment, according to which agreements such as those at issue in that case may constitute restrictions of competition

by object, was based primarily on the existence in those agreements of no-challenge clauses applying to the patents in dispute. In so far as the agreements at issue here did not contain such no-challenge clauses, the General Court erred in classifying them as restrictions of competition by object. The absence of no-challenge clauses in the agreements at issue shows that the generic manufacturers refrained from challenging the patents in dispute as a result not of those agreements, but as a result of the generic manufacturers' autonomous assessment of the strength of Lundbeck's patents.

145. However, that line of argument must also fail.

146. Thus, irrespective of whether the agreements at issue in *Generics (UK) and Others* contained explicit no-challenge clauses applying to the patent concerned or whether the obligation not to challenge that patent resulted solely from the context and general scheme of those agreements, (86) the fact remains that, in any event, the absence of explicit no-challenge clauses in the agreements at issue in this case is not a factor capable of calling into question the General Court's assessment that those agreements constituted restrictions of competition by object.

147. Thus, the appellants do not put forward any arguments capable of casting doubt on the General Court's finding in paragraphs 398 and 399 of the judgment under appeal that, even though the agreements at issue did not contain no-challenge clauses, the generic manufacturers had no incentive to challenge Lundbeck's patents after concluding those agreements, since the reverse payments broadly corresponded to the profits they could have expected to make if they had entered the market or to the damages they could have obtained if they had succeeded in litigation against Lundbeck, and that even if those payments were less than the expected profits, they nevertheless constituted a certain and immediate profit, which those manufacturers obtained without necessitating the risks that market entry would have entailed.

148. Those considerations are all the more valid since it follows from the facts analysed by the General Court that, under the agreements at issue, Lundbeck's payments to the generic manufacturers had to be made, at least in part, in instalments over the term of those agreements. (87) It is unlikely, in view of the general scheme of the agreements, that they would have started from the premiss that Lundbeck would continue to pay the generic manufacturers for their undertakings if they also brought actions challenging the validity of the patents in dispute.

149. Moreover, for the same reasons, Lundbeck's argument that the agreements at issue did not prevent the generic manufacturers from entering the market with non-infringing products is wholly unconvincing. First of all, that argument is again based on the incorrect premiss that it was established that the products of the generic manufacturers in question infringed Lundbeck's patents, when that was in fact unclear. (88) In addition, it is simply unlikely that the generic manufacturers retained an incentive to enter the market with citalopram of any kind when they were moreover being paid by Lundbeck not to call into question the validity of the patents it still held relating to that compound. (89)

(4) Allegation that it was novel for a penalty to be imposed in respect of patent dispute settlements

150. Fourthly, the appellants submit that since the agreements at issue pursued the legitimate objective of settling a patent dispute, they cannot simply be treated as undisguised market exclusion agreements revealing a sufficient degree of harm to competition to be classified as restrictions of competition by object. This is all the more so because, at the time the agreements at issue were concluded, there was a great deal of uncertainty as regards how patent settlement agreements would be assessed under competition law.

151. That line of argument is not convincing either.

152. Thus, as the General Court correctly found in the judgment under appeal, (90) it follows from the case-law of the Court of Justice that neither the fact that an agreement pursues the legitimate objective of settling a dispute (91) nor the fact that it concerns an intellectual property right (92) shields such an agreement from the full application of the rules of EU competition law. The judgments relied on by the

appellants in that regard are not capable of supporting the view that, in general, agreements in the field of intellectual property are not capable of restricting competition. (93)

153. Moreover, the appellants do not put forward any evidence capable of invalidating the General Court's findings confirming the Commission's conclusion that, in the present case, the agreements at issue did not serve to bring an end to the underlying patent disputes between the parties to those agreements. (94) The mere fact that the term of the agreements at issue was dependent on the outcome of a test case between Lundbeck and another manufacturer of generic medicinal products in the United Kingdom does not demonstrate that those agreements resolved the underlying patent disputes, when they simply put those disputes on hold for the agreed period.

154. Furthermore, the appellants cannot rely on an alleged lack of experience in the penalties imposed under competition law in respect of agreements similar to those at issue here, or on the fact that the Konkurrence- og Forbrugerstyrelsen (Authority for the protection of competition and consumers, Denmark) ('KFST') and the Commission themselves harboured doubts, at the outset, as to the legal characterisation of those agreements, in order to argue that the latter cannot be treated as restrictions of competition by object.

155. Contrary to the appellants' view, the fact that this is the first case in which the Commission has applied Article 101 TFEU to patent dispute settlement agreements between an originator undertaking and generic manufacturers in the pharmaceutical field does not mean that those agreements cannot be characterised as restrictions of competition by object for the purpose of that provision.

156. As the General Court correctly stated in paragraphs 438 and 774 of the judgment under appeal, it is not necessary, in order to classify an agreement as a restriction of competition by object, that the same type of agreement has been found unlawful in the past. The role of experience and, therefore, foreseeability in that regard do not, as the General Court correctly explained, concern the specific category of an agreement in a particular sector, but the fact that it is established that certain forms of collusion, such as the exclusion of competitors from the market, are, in general and in view of the experience gained, so likely to have negative effects on competition that it is not necessary to demonstrate that they had such effects in the particular case at hand.

157. Furthermore, the General Court was also right to point out, in paragraphs 752 and 775 of the judgment under appeal, that the case-law does not require that an agreement be prima facie or undoubtedly sufficiently harmful to competition, without a detailed examination of its content, its purpose and the legal and economic context in which it occurs, in order to be regarded as a restriction of competition by object for the purpose of Article 101 TFEU. (95)

(5) Conclusion

158. It follows from the above considerations that the appellants have not put forward any arguments capable of demonstrating that the General Court was wrong to confirm the Commission's conclusion that the agreements at issue constituted restrictions of competition by object, even assuming that they imposed on the generic manufacturers restrictions that Lundbeck could also have obtained by means of legal proceedings based on the patents in dispute if the validity of those patents and the infringing nature of the generic products had been established. The first ground of appeal must therefore be dismissed.

(b) Alleged error in that the General Court found that five of the six agreements went beyond the scope of Lundbeck's patents (second ground of appeal)

159. In their second ground of appeal, the appellants submit that the General Court erred in finding that five of the six agreements at issue went beyond the scope of Lundbeck's patents, in so far as they prohibited not only the sale of citalopram that potentially infringed the processes protected by the patents in dispute, but the sale of any kind of citalopram, regardless of how it was produced.

160. It should be noted at the outset that this ground of appeal is both ineffective and inadmissible.

161. Thus, it is apparent from the Court's settled case-law that arguments directed against grounds of a decision of the General Court included purely for the sake of completeness cannot lead to the annulment of that decision and are therefore ineffective. (96)

162. In the present case, the General Court expressly noted, in paragraphs 539 to 541 of the judgment under appeal, that the appellants' arguments alleging that the decision at issue was incorrect in that it wrongly concluded that the agreements at issue contained restrictions going beyond those inherent in the exercise of the rights their patents conferred on them was ineffective.

163. According to the General Court, even if the agreements at issue had not exceeded the scope of the appellants' patents, those agreements would still have constituted restrictions of competition by object for the purpose of Article 101 TFEU, since they consisted in agreements intended to delay the market entry of the generic manufacturers, in exchange for significant reverse payments, which transformed the uncertainty in relation to that market entry into the certainty that it would not take place during the term of the agreements at issue.

164. Accordingly, it was only in the alternative that the General Court examined, in paragraphs 542 to 705 of the judgment under appeal, the appellants' arguments claiming that the Commission had erred in finding that the restrictions imposed by the agreements at issue went beyond the scope of the patents in dispute. (97)

165. That the Commission took account of the fact that the agreements at issue contained restrictions going beyond the scope of the patents in dispute both when finding that those agreements were anticompetitive and when determining the amount of the fines does not, moreover, call into question the ineffectiveness of those arguments at first instance. The General Court clearly pointed out that that issue had been a relevant, but not decisive, factor in the decision at issue in establishing the existence of a restriction by object for the purpose of Article 101 TFEU and in determining the level of the fines. (98)

166. It must also be noted, as the Commission does, that, in any event, the second ground of appeal is inadmissible.

167. It is true that the appellants claim that their line of argument consists of alleging that the General Court erred in law by failing to apply the appropriate legal test when examining whether the restrictions imposed by the agreements at issue went beyond the scope of the patents in dispute. Thus, they submit that the General Court should have examined, with reference to the principles of contract law in each of the legal systems concerned by the agreements at issue, whether prohibiting the generic manufacturers from entering the markets concerned with any type of citalopram, not only the citalopram considered by Lundbeck to infringe its patents, actually reflected the meeting of minds between Lundbeck and the generic manufacturers.

168. However, under cover of that line of argument, the appellants actually seek to have the Court of Justice re-examine the General Court's interpretation of the wording of the agreements and of the facts surrounding their conclusion, which is — save where the clear sense of the facts is distorted, which in this case is neither alleged nor apparent — inadmissible at the appeal stage. (99)

169. It follows that the second ground of appeal must be rejected, without there being any need to consider the substance of the arguments put forward to support it by the appellants.

(c) Alleged error in classifying some of the agreements at issue as restrictions of competition by object even if they are assumed to go beyond the scope of the patents in dispute (third ground of appeal)

170. By their third ground of appeal, the appellants claim that even if the Court were to find that some of the agreements at issue went beyond the scope of the patents in dispute by prohibiting the sale of any

generic citalopram, the General Court was nevertheless wrong to conclude that those agreements constituted restrictions of competition by object.

171. In support of that claim, the appellants refer to the arguments put forward in support of the first ground of appeal. Thus, they submit that the General Court erred in classifying the agreements at issue as restrictions of competition by object, since it took insufficient account of the context of those agreements, notably the asymmetry of risks between Lundbeck and the generic manufacturers, failed to examine the counterfactual scenario, and wrongly concluded that the agreements were sufficiently harmful to competition to be classified as restrictions of competition by object, particularly in view of the initial doubts that the KFST and the Commission themselves had in that regard.

172. However, since those arguments have already been rejected in the examination of the first ground of appeal above, (100) the third ground of appeal must also fail.

B. Fines (fifth and sixth grounds of appeal)

173. By their fifth and sixth grounds of appeal, the appellants submit that the General Court erred in upholding the fines imposed by the Commission as a matter of principle (1) and as regards their method of calculation (2).

1. Confirmation of the fines by the General Court (fifth ground of appeal)

174. In their fifth ground of appeal, the appellants argue that the General Court was wrong to confirm that the Commission was entitled to impose fines on Lundbeck in this case. Thus, first of all, the General Court did not apply the correct test to determine whether a fine could be imposed here (a). Next, the General Court erred in upholding the Commission's finding that Lundbeck could not have been unaware of the anticompetitive nature of its conduct (b). Last, the General Court disregarded the principles of legal certainty and non-retroactivity by confirming the imposition of a penalty exceeding the level of a symbolic fine (c).

(a) The 'standard for culpability' required for the imposition of a fine

175. The appellants submit that the General Court did not apply the correct test regarding the 'standard for culpability' required for the imposition of a fine under competition law. Thus, the General Court did indeed state, in paragraph 762 of the judgment under appeal, that, according to the case-law of the Court of Justice, the imposition of such a fine is possible only if an undertaking 'cannot be unaware of the anticompetitive nature of its conduct'. However, the General Court did not then apply that test to determine Lundbeck's culpability; on the contrary, it simply stated in paragraph 777 of the judgment under appeal that the agreements at issue 'could reasonably have been perceived' by Lundbeck as being in breach of Article 101 TFEU, thus incorrectly lowering the standard for culpability required for the imposition of a fine.

176. As a preliminary point, it should be noted that it is clear from the case-law of the Court of Justice, cited by the General Court in paragraph 762 of the judgment under appeal, that, with regard to whether an infringement of competition law has been committed intentionally or negligently and is therefore liable to be penalised by the imposition of a fine in accordance with Article 23 of Regulation (EC) No 1/2003, (101) that condition is satisfied where the undertaking concerned cannot be unaware of the anticompetitive nature of its conduct, whether or not it is aware that it is infringing the competition rules of the Treaty. In particular, the fact that the undertaking concerned has characterised wrongly in law its conduct upon which the finding of the infringement is based cannot have the effect of exempting it from imposition of a fine. (102)

177. That stated, it must be held that, in the judgment under appeal, the General Court did not fail to apply the test established by the case-law.

178. First of all, it should be pointed out, as the Commission did, that contrary to the appellants' assertions, the fact that it must be established that an undertaking 'could not have been unaware' of the anticompetitive nature of its conduct does not mean that the Commission is required to show with certainty that that undertaking was aware of that anticompetitive nature. In other words, it is not necessary to prove that the undertaking in question knew that its conduct was anticompetitive. On the contrary, it is sufficient for the Commission to adduce evidence showing that, in the given circumstances, a diligent economic operator could reasonably have been expected to be aware of the anticompetitive nature of its conduct.

179. The appellants are therefore playing with words when they claim that the General Court failed to apply that standard of proof in the present case by noting, in paragraph 777 of the judgment under appeal, that the restrictions on competition set out by the agreements at issue 'could reasonably have been perceived' by the parties as being in contrary to Article 101 TFEU. In contrast to the appellants' assertions, it does not in fact follow from that wording that the General Court was satisfied with a standard of proof whereby it was sufficient that it 'was possible' that Lundbeck was aware of the anticompetitive nature of its conduct. Furthermore, in paragraphs 832 and 833 of the judgment under appeal, the General Court clearly stated that Lundbeck 'could not have been unaware' that the agreements at issue were capable of infringing Article 101 TFEU and that it 'was aware' of the potentially infringing nature of those agreements.

180. The first part of the fifth ground of appeal must therefore be rejected.

(b) Whether Lundbeck could not have been unaware of the anticompetitive nature of its conduct

181. The appellants also submit that the General Court failed to apply the standard of proof required for the imposition of a fine, since the evidence relied on by the General Court is not capable of demonstrating that Lundbeck could not have been unaware of the anticompetitive nature of its conduct.

182. Thus, in so far as the agreements at issue cannot be treated in the same way as mere market sharing or market exclusion agreements, but instead involved the implementation of intellectual property rights in pursuit of a legitimate aim, their anticompetitive nature was much more difficult to grasp than that of undisguised market sharing agreements. Notwithstanding this, in paragraph 776 of the judgment under appeal, the General Court relied on only two documents to establish Lundbeck's culpability, even though it can in no way be inferred from those documents that Lundbeck could not have been unaware of the anticompetitive nature of its conduct. According to the appellants, the General Court therefore manifestly distorted the evidence and failed to provide a sufficient explanation as to why it confirmed Lundbeck's culpability.

183. Those arguments are without substance.

184. In the first place, it follows from the considerations set out above that the appellants have no basis for claiming that the agreements at issue did not constitute market exclusion agreements, and that the backdrop to those agreements concerning patents cannot serve as a pretext for shielding them from the full application of the rules of competition law. (103)

185. In the second place, it must be stated that it is not apparent how the General Court distorted the three documents (not two, as the appellants stated) cited in paragraph 776 of the judgment under appeal when it took those documents into account in its examination of whether Lundbeck could not have been unaware of the anticompetitive nature of its conduct:

– thus, first, in paragraph 776 of the judgment under appeal, the General Court refers to recital 190 of the decision at issue to support its assertion that some generic manufacturers were indeed aware of the infringing nature of agreements similar to the agreements at issue and refused to enter into such agreements for that reason. Recital 190 of the decision at issue cites an email from NM Pharma to Lundbeck, filed in a Lundbeck document entitled 'Generic citalopram update 04 09 2002', which shows that NM Pharma declined Lundbeck's invitation to a meeting, stating that its 'Antitrust

Policy' prevented it from engaging in further discussions with Lundbeck. Accordingly, the General Court did not distort that document by relying on it as evidence to support the finding that Lundbeck could not have been unaware of the anticompetitive nature of its conduct;

– secondly, in paragraph 776 of the judgment under appeal, the General Court cites an email from an employee of Lundbeck, mentioned in recital 265 of the decision at issue. In that document, the employee concerned objected to a proposal made by Lundbeck to Merck (GUK) with a view to reaching an agreement, during the negotiations prior to the Merck (GUK) agreement for the United Kingdom, on the resale prices of citalopram to be supplied by Lundbeck to Merck (GUK) under that agreement, stating that it was unlawful to agree resale prices. It follows that the General Court also did not distort that document by including it in the body of evidence showing that Lundbeck could not have been unaware of the anticompetitive nature of its conduct;

– thirdly, in paragraph 776 of the judgment under appeal, the General Court refers to an internal email of Lundbeck, mentioned in recital 188 of the decision at issue, reporting that, regarding the negotiations with Ranbaxy, an agreement would be difficult, particularly from the perspective of competition law. In view of this, it is not apparent how the General Court distorted that document by taking it into account to support its assertion that Lundbeck could not have been unaware of the anticompetitive nature of its conduct.

186. In the third and last place, and in any event, it is the appellants themselves who distort the judgment under appeal, claiming that the General Court relied solely on the documents examined in the preceding points in order to find that Lundbeck could not have been unaware of the anticompetitive nature of its conduct, and that it did not give sufficient reasons for that finding.

187. Thus, it follows from the General Court's considerations in paragraphs 764 to 776 of the judgment under appeal that the conclusion reached in paragraph 777 of that judgment, according to which the restrictions of competition resulting from the agreements at issue could reasonably have been perceived by the parties to those agreements as being contrary to Article 101(1) TFEU, is based not only on the factual evidence set out in paragraph 776, but on all the considerations in paragraphs 764 to 776.

188. In those considerations, the General Court fully explained the reasons for its conclusion that Lundbeck could have reasonably foreseen the anticompetitive nature of its conduct. Thus, in paragraph 764 of the judgment under appeal, the General Court stated, in particular, that it was not unforeseeable that agreements by which an originator undertaking is able to remove potential competitors from the market for a specified period, by means of significant reverse payments, might be contrary to Article 101(1) TFEU, whether or not they go beyond the scope of that undertaking's patents.

189. In addition, as the Commission rightly pointed out, it is apparent from a number of paragraphs of the judgment under appeal that the General Court confirmed the Commission's assessment of various items of factual evidence which, in addition to those referred to in paragraph 776 of the judgment under appeal, were capable of showing that Lundbeck could not have been unaware of the anticompetitive nature of its conduct, or even that it was aware of that anticompetitive nature. (104) The appellants do not call into question in this appeal the factual assessments thus carried out by the General Court, nor does it appear that the General Court distorted relevant factual evidence.

190. In those circumstances, the second part of the fifth ground of appeal must also be rejected.

(c) Principles of legal certainty and non-retroactivity

191. In the third part of their fifth ground of appeal, the appellants submit that, by confirming the imposition on Lundbeck of more than a symbolic fine, the General Court infringed the principles of legal certainty and non-retroactivity.

192. According to the appellants, those principles prohibit the retroactive application of a new interpretation of a provision establishing an infringement, if that interpretation was not reasonably foreseeable when the infringement was committed. That is precisely the case with the interpretation adopted by the Commission and upheld by the General Court here, according to which agreements such as the agreements at issue may be caught by the prohibition laid down in Article 101 TFEU.

193. That argument cannot succeed.

194. Thus, it is indeed apparent from the case-law relied on by the appellants that, although the principle that offences and penalties are to be strictly defined by law, now enshrined in Article 49 of the Charter of Fundamental Rights of the European Union, cannot be interpreted as prohibiting the gradual clarification of the rules of criminal liability, that principle nevertheless precludes the retroactive application of the judicial interpretation of a rule establishing an offence the result of which was not reasonably foreseeable at the time the offence was committed, especially in the light of the interpretation put on the provision in the case-law at the material time. (105)

195. Nevertheless, it must be held that the General Court did not err in applying the foreseeability test thus established to the circumstances of the present case and in finding that, in this instance, the principle that offences and penalties are to be strictly defined by law did not prevent penalties being imposed in respect of the agreements at issue on the basis of Article 101 TFEU.

196. In that regard, the appellants restate, first of all, their argument mentioned previously above (106) to the effect that the agreements at issue involved the implementation of intellectual property rights in pursuit of a legitimate aim, so that their nature was much more difficult to grasp than that of undisguised market sharing agreements. Consequently, contrary to the General Court's assertion in paragraph 765 of the judgment under appeal, a literal reading of Article 101(1) TFEU does not make it clear that such agreements are liable to be caught by the prohibition laid down in that provision.

197. It is, however, clear from the General Court's findings examined above that the purpose of the agreements at issue was to induce the generic manufacturers to refrain from entering the citalopram market independently during the agreed periods, by means of payments from Lundbeck the only consideration for which was that undertaking to refrain. (107) In other words, those agreements stipulated that Lundbeck would pay the generic manufacturers not to enter the market, thus rendering them market exclusion agreements.

198. As a party to those agreements, Lundbeck could not have been unaware that the only consideration it received from the generic manufacturers for its payments was their undertaking not to enter the market during the agreed periods. Therefore, the General Court did not err in finding, in paragraphs 764 and 765 of the judgment under appeal, that it was not unforeseeable from Lundbeck's perspective that the agreements at issue might be caught by the prohibition laid down in Article 101 TFEU, since a literal reading of that provision makes it quite clear that agreements between competitors aimed at excluding some of them from the market are unlawful.

199. Moreover, it is also apparent from the considerations set out above that the appellants have no basis for claiming that the backdrop to the agreements at issue in terms of patent law could have led them to believe that those agreements would be shielded from the application of competition law. It follows from the Court's settled case-law that both a court settlement and the conditions for the exercise of an intellectual property right may fall within the prohibitions laid down in Article 101 TFEU. (108)

200. Accordingly, contrary to the appellants' assertions, the General Court was correct to state, in paragraphs 766 to 770 of the judgment under appeal, that the fact that, in the present case, the agreements at issue had been concluded in the form of settlement agreements covering intellectual property rights could not allow the appellants to infer that their unlawfulness under competition law was completely novel or unforeseeable.

201. In addition, contrary to the view taken by the appellants, the fact that this is the first case in which the Commission has applied Article 101 TFEU to patent dispute settlement agreements between an originator undertaking and generic manufacturers in the pharmaceutical field does not mean that such application constitutes a 'completely new approach' that cannot be regarded as a gradual clarification of the conditions for the application of that provision within the meaning of the case-law cited in paragraph 194 of this Opinion. As already noted, in order for an agreement to be classified as a restriction of competition by object, it is not necessary for the same type of agreement to have been found unlawful in the past or for that agreement to be prima facie or undoubtedly sufficiently harmful to competition. (109)

202. On that basis, the appellants are also not able to rely on the alleged 'complex' nature of the agreements at issue to argue that imposing a penalty in respect of them under Article 101 TFEU was not foreseeable. That is all the more so because case-law has made clear that a law may still satisfy the requirement of foreseeability even if the individuals concerned, particularly persons carrying on a professional activity, have to take appropriate legal advice to assess the consequences of their actions. (110) Similarly, as indicated above, it follows from case-law that the fact that the undertaking concerned has characterised wrongly in law its conduct upon which the finding of the infringement is based cannot have the effect of exempting it from imposition of a fine in so far as it could not have been unaware of the anticompetitive nature of that conduct. (111)

203. Lastly, the appellants' argument that the General Court did not sufficiently explain or clarify why, in its view, they should have expected the agreements at issue to attract a penalty under Article 101 TFEU, when the KFST and the Commission themselves had doubts in that regard, also has no prospect of succeeding.

204. Thus, the General Court stated, in paragraph 772 of the judgment under appeal, that it was clear from the KFST's press release relied on by the appellants that agreements whose object is to acquire market exclusion of a competitor are anticompetitive. Similarly, the General Court noted in that paragraph that the Commission was able to refine its approach following its investigation of the pharmaceutical sector and thus fully comprehend the anticompetitive nature of agreements such as those at issue here.

205. Contrary to what the appellants seem to suggest, that explanation is not vitiated by errors of substance either. Thus, as noted above, (112) the anticompetitive nature of an agreement does not have to be prima facie or undoubtedly self-evident in order for the agreement to be classified as a restriction of competition by object. Accordingly, the fact that the Commission needs to conduct thorough investigations before classifying certain conduct as restrictions of competition does not mean that the anticompetitive nature of such conduct is not foreseeable for the economic operators taking part in it. That is all the more so since, as the Commission rightly pointed out, unlike that authority, which must first investigate the facts, the operators involved have full knowledge of those facts. Therefore, in the present case, unlike the Commission, Lundbeck knew from the outset that the only consideration for its payments to the generic manufacturers under the agreements at issue was the latter's undertaking that they would refrain from entering the market with their products.

206. It follows from the foregoing that the third part of the fifth ground of appeal must also be rejected, as must, in consequence, the fifth ground of appeal in its entirety.

2. Confirmation by the General Court of the fine calculations (sixth ground of appeal)

207. By their sixth ground of appeal, the appellants submit that the General Court erred in confirming the inclusion by the Commission, for the purpose of calculating the amount of the fines imposed on Lundbeck, of sales by Lundbeck that could not have been affected by the agreements at issue (a). The appellants also claim that the General Court was wrong to uphold the gravity percentage applied by the Commission to calculate the amount of the fines imposed on Lundbeck (b).

(a) Sales by Lundbeck taken into account for the purpose of calculating the amount of the fines

208. It follows from paragraphs 68 and 70 to 75 of the judgment under appeal and from the recitals of the decision at issue to which those paragraphs refer (113) that, in order to calculate the amount of the fines imposed on Lundbeck, the Commission followed the general methodology set out in the Guidelines on the method of setting fines imposed pursuant to Article 23(2)(a) of Regulation No 1/2003 ('the 2006 Guidelines'), (114) based on the value of sales of the relevant product made by each participant in an infringement in the relevant geographic area. Furthermore, as mentioned above, (115) the Commission imposed four separate fines on Lundbeck, since the six agreements at issue were considered to give rise to four separate infringements: the two agreements between Lundbeck and Merck (GUK) were classified as a single and continuous infringement, as were the two agreements between Lundbeck and Arrow.

209. Therefore, in order to calculate each fine, the Commission took account of Lundbeck's sales of citalopram in the geographic markets concerned by each of the four infringements.

210. In the first part of their sixth ground of appeal, the appellants submit that, by endorsing that fine calculation method, the General Court erred in law.

211. According to the appellants, the Commission was wrong to include in its calculation of the amount of the fines all sales of citalopram made by Lundbeck during the term of the agreements at issue in the geographic sectors concerned by those agreements, (116) when some of those sales could not have been affected by the agreements in question. The reason for this is that the generic manufacturers were unable to enter the markets of some Member States during the term of the agreements at issue because, first, they did not secure MAs in a significant number of those States until after the expiry of those agreements and, secondly, the citalopram compound patent was still in force in Austria for a large part of their term, because it expired only in April 2003.

212. The appellants claim that, in order to take account of an undertaking's sales for the purpose of calculating the amount of a fine under the method in question, the Commission is required to examine whether those sales were actually affected by the infringement. In the present case, that would have entailed carrying out a detailed examination of the specific prospects that the generic manufacturers had of actually entering the market of each Member State concerned by the agreements at issue during the term of those agreements. If the generic manufacturers were unable to enter the market of a Member State during the relevant period, Lundbeck's sales in that State could not be affected by the agreements at issue either. Therefore, all sales made in periods during which the generic manufacturers did not have MAs in the Member States concerned or during which the citalopram compound patent was still in force in Austria should be excluded from the value of Lundbeck's sales used for the purpose of calculating the amount of the fine.

213. In the judgment under appeal, the General Court rejected that line of argument, finding, in paragraph 804 thereof, that as infringements by object were involved, the Commission was entitled to rely on the geographic scope of the agreements at issue as a whole for the purpose of calculating the amount of the fines, without carrying out a detailed examination of the specific entry prospects of the generic manufacturers in each State concerned. Moreover, in paragraph 815 of the judgment under appeal, the General Court explained that the appellants' reasoning had to be rejected because it effectively denied the distinction between actual competition and potential competition and the fact that Article 101 TFEU also protects the latter.

214. Contrary to the appellants' assertions, those findings are not vitiated by any error of law.

215. The appellants submit that their view is supported by paragraphs 6 and 13 of the 2006 Guidelines, according to which 'the combination of the value of sales *to which the infringement relates* and of the duration of the infringement is regarded as providing an appropriate proxy to reflect the economic importance of the infringement as well as the relative weight of each undertaking in the infringement', so that the Commission, when applying the calculation method in question, uses 'the value of the undertaking's sales of goods or services *to which the infringement directly or indirectly relates* in the relevant geographic area'. (117)

216. However, the appellants' argument — to the effect that the sales of citalopram made by Lundbeck during the term of the agreements at issue in the States covered by the scope of those agreements constitute sales 'to which the infringement relates' within the meaning of those paragraphs only if the generic manufacturers had an MA for their products in each of the States concerned — cannot succeed. The same applies to the argument claiming that it was impossible to place generic citalopram on the market in Austria during part of the term of those agreements due to the existence of a patent protecting the API of that medicinal product.

217. It follows from the Court's settled case-law that paragraph 13 of the 2006 Guidelines pursues the objective of adopting as the starting point for the calculation of the amount of the fine imposed on an undertaking an amount which reflects the economic significance of the infringement and the size of the undertaking's contribution to it. Consequently, while the concept of the value of sales referred to in paragraph 13 of the 2006 Guidelines admittedly cannot extend to encompassing sales made by the undertaking in question which do not fall within the scope of the alleged cartel, it would however be contrary to the goal pursued by that provision if that concept were understood as applying only to turnover achieved by the sales in respect of which it is established that they were actually affected by that cartel. (118)

218. Limiting the sales taken into account for the purpose of calculating a fine solely to sales in respect of which it is established that they were actually affected by a cartel would have the effect of artificially minimising the economic significance of the infringement committed by a particular undertaking and would lead to the imposition of a fine which bore no actual relation to the scope of application of the infringement in question. (119)

219. That is so, in particular, because limiting the sales taken into account for the purpose of calculating a fine solely to sales in respect of which it is established that they were actually affected by a cartel would effectively disregard the fact that one of the main objectives of numerous cartels is to achieve a stabilisation effect that naturally benefits the whole activity of the cartel participants on the relevant market. If, however, the unlawful object of the cartel encompasses the entire market, then all sales made on that market must also be taken as a basis for calculating the amount of the fines. (120)

220. In the present case, the purpose of the agreements at issue was specifically to protect Lundbeck's sales of citalopram in the geographic area concerned by each of them, as the Commission found in recital 1325 of the decision at issue and pointed out at the hearing in these proceedings.

221. As noted above, by means of those agreements, Lundbeck eliminated the risk of the generic manufacturers entering all of the markets concerned, by inducing them through the medium of payments to relinquish their efforts, during the agreed periods, to prepare to enter and actually enter those markets with their products. (121) Accordingly, by means of the agreements at issue, Lundbeck eliminated potential competition from the generic manufacturers in relation to citalopram. (122)

222. As the General Court rightly found in the judgment under appeal, the fact that a generic manufacturer does not yet have an MA for its product in a particular State does not preclude the existence of potential competition between that manufacturer and an originator undertaking already active in the relevant geographic area. In addition, the General Court found that, in the present case, not only had the generic manufacturers been seriously preparing their market entry for a long time, they also already had MAs or had taken steps to obtain them in the short or medium term. Therefore, each of the generic undertakings had real and concrete possibilities of obtaining MAs and thus entering the citalopram market in several EEA countries within a sufficiently short period to exert competitive pressure on Lundbeck. (123)

223. Similarly, the fact that the patent protecting the citalopram compound or its original manufacturing processes was still in force in Austria for part of the term of the agreements at issue (124) was not a bar to the existence of potential competition in that Member State at that time. Such potential competition may be exerted long before the expiry of a patent protecting the active ingredient of an originator medicinal product, since the manufacturers of generic medicinal products want to be ready to enter the market as

soon as that patent expires. (125) That is particularly true in a case such as this, in which the agreements were concluded a relatively short period of time before the expiry of the patent protecting citalopram in Austria and some of the generic manufacturers had already taken steps to obtain MAs in that country at that time. Indeed, Alpharma obtained that MA during the term of its agreement with Lundbeck. Thus, the generic manufacturers had real and concrete possibilities of entering the market in Austria within a sufficiently short period of time to exert competitive pressure on Lundbeck even during the period when the patent protecting the citalopram compound or its original manufacturing processes was still in force in that Member State, at which time the agreements at issue had already been concluded. (126)

224. Consequently, in so far as Lundbeck eliminated that competitive pressure by means of the agreements at issue for all its sales in the territories and during the periods concerned by those agreements, all of those sales also constitute sales 'to which the infringement relates' within the meaning of paragraphs 6 and 13 of the 2006 Guidelines.

225. As is apparent from the case-law cited above, (127) in order to be able to take sales into account for the purpose of calculating the amount of the fine imposed on an undertaking, the conclusive factor is not whether each commercial transaction entered in the accounts is actually the result of the cartel in question. Instead, it is sufficient that the object or effect of the cartel was to distort competition on the relevant market on which those transactions took place. In that case, in principle the whole of the turnover achieved on that market is to be included in calculating the amount of the fine. (128)

226. This holds true irrespective of whether effective competition or, as in the present case, potential competition was eliminated in a given market. As the General Court held, if it were possible to pay competitors to cease or slow down their preparations for market entry, effective competition would never take place or would suffer significant delays. (129) Accordingly, the Commission was right to state at the hearing in the present case that the proposition that fines may be imposed only for the period in respect of which the Commission is able to demonstrate with certainty that potential competition could have developed into effective competition must be rejected.

227. If that proposition were upheld, the effectiveness of Article 101 TFEU would be totally undermined, since its effect would be to allow undertakings to eliminate potential competition with impunity, on the ground that it has not been proven that the sales made on the market concerned by that elimination were actually affected by the infringement in question and may, consequently, be taken into account for the purpose of calculating the amount of the fine.

228. That is all the more true here because, as the Commission also rightly pointed out at the hearing in this case, it is impossible to ascertain whether it was precisely the agreements at issue themselves that dissuaded the generic manufacturers from expediting the steps required to obtain an MA for their products in the States concerned by those agreements or whether it was Lundbeck's other steps that delayed the issue of such MAs. (130)

229. Lastly, contrary to the appellants' claims, the method of calculating the value of Lundbeck's sales that was used to calculate the amount of the fines in the present case is also not incompatible with the General Court's previous decisions in *E.ON Ruhrgas and E.ON* v *Commission* (131) and *Telefónica* v *Commission*. (132)

230. Thus, the appellants submit, first, that the General Court failed to give sufficient reasons for the distinction it drew in paragraph 816 of the judgment under appeal between this case and *E.ON Ruhrgas and E.ON* v *Commission*, in which it acknowledged that legal or factual barriers precluded the existence of any competition for part of the period under consideration. (133)

231. The General Court explained in paragraph 816 of the judgment under appeal that the circumstances in *E.ON Ruhrgas and E.ON* v *Commission* were not comparable to those of the present case since, in *E.ON Ruhrgas and E.ON* v *Commission*, no competition was possible, even in the absence of an anticompetitive agreement, for part of the period considered, due to national legislation establishing a de facto monopoly.

On the other hand, the General Court found in the instant case that the appellants had failed to demonstrate that, in the absence of the agreements at issue, competition — even potential competition — between them and the generic manufacturers would have been impossible or non-existent.

232. According to the appellants, those findings do not rebut the argument that the generic manufacturers were, like the operators at issue in *E.ON Ruhrgas and E.ON* v *Commission*, de facto prevented from competing with Lundbeck on the markets of the States for which they did not have MAs. They submit that the argument that preparations for obtaining an MA point to the existence of potential competition cannot succeed because, in *E.ON Ruhrgas and E.ON* v *Commission*, the possibility of preparing for market entry was also not considered to demonstrate the existence of potential competition during a period when the existence of a monopoly continued to prevent the operators concerned from penetrating the market in question. (134)

233. However, as the Commission states, in essence, a situation in which legislation or a matter of fact prevents all competition on a market, even potential competition, is not comparable to a situation in which a market is open to competition, even if operators wishing to enter that market must meet certain conditions in order to do so, such as, for example, obtaining an MA for their products.

234. In other words, in the present case, there was no legislation or matter of fact preventing the generic manufacturers from taking steps to obtain an MA and from entering the markets concerned as soon as they had the MA in their possession, whereas, in *E.ON Ruhrgas and E.ON* v *Commission*, the operators were, irrespective of their intentions or the steps taken, *de jure* or de facto prevented from entering the relevant markets for as long as the legal or factual barriers to entry to those markets remained in place. The General Court therefore explained to the requisite legal standard and was right to find that the lack of MAs in this case did not in any way amount to a barrier to market entry precluding the existence of all competition, even potential competition, in the same way as the barriers at issue in *E.ON Ruhrgas and E.ON* v *Commission*. The same is true of the situation in Austria, where the existence of the original patent, which was already nearing its expiry date, did not prevent the existence of potential competition between the parties for the reasons explained above. (135)

235. Secondly, the circumstances of the present case are not comparable to those in *Telefónica* v *Commission* either, which was also relied on by the appellants. In that case, the General Court found that it had not been established that all the sales taken into account for the purpose of calculating the amount of the fine related to activities for which the parties to an agreement were potential competitors, so that that question had to be reconsidered by the Commission. (136) By contrast, in the present case, the appellants did not challenge the General Court's findings establishing that Lundbeck and the generic manufacturers were potential competitors on all the markets covered by the scope of the agreements at issue. (137)

236. As regards, thirdly, the appellants' argument that the effects of an infringement may be relevant for the calculation of the fine amount even in the case of an infringement by object, (138) suffice it to note that, under paragraph 22 of the 2006 Guidelines, the Commission has regard not to the effects of the infringement, but to whether or not it has been implemented, and that, in the present case, the appellants do not dispute the General Court's findings that the agreements at issue were implemented. (139)

237. Furthermore, and in any event, it has in no way been demonstrated that, in this case, the agreements at issue did not produce effects during the periods when the generic manufacturers were not yet in possession of MAs for their products. It is doubtful to say the least that no such effects were produced in so far as it has been established that those agreements were specifically intended to eliminate, during the agreed periods, potential competition between Lundbeck and the generic manufacturers by inducing the latter to relinquish their efforts to prepare to enter the market and, therefore, to obtain MAs. (140)

238. It follows that the first part of the sixth ground of appeal must be rejected.

(b) The gravity percentage applied for the purpose of calculating the amount of the fines

239. In accordance with paragraph 19 et seq. of the 2006 Guidelines, the basic amount of the fine is to be related to a proportion of the value of sales, depending on the degree of gravity of the infringement, which is assessed on a case-by-case basis taking account of all the relevant circumstances of the case.

240. It follows from paragraph 72 of the judgment under appeal and from the recitals of the decision at issue to which that paragraph refers (141) that, in the present case, the Commission classified the infringements as 'serious' on account of (i) the fact that they entailed market exclusion; (ii) Lundbeck's high market share for the products in question; (iii) the very wide geographic scope of the agreements at issue; and (iv) the fact that all the agreements had been implemented. The Commission ultimately set the proportion of the value of sales to be taken into account for the purpose of calculating the amount of the fines at 11% for the infringements covering the entire EEA, that is to say, for the agreements concluded with Merck, Alpharma and Ranbaxy, and at 10% for the infringement arising from the agreements concluded with Arrow, which covered only the United Kingdom and Denmark. (142)

241. In the second part of their sixth ground of appeal, the appellants submit that, by endorsing the gravity percentages thus applied by the Commission, the General Court erred.

242. Before addressing that line of argument, it must be borne in mind that the General Court alone has jurisdiction to examine how in each particular case the Commission appraised the gravity of unlawful conduct. In an appeal, the purpose of review by the Court of Justice is, first, to examine to what extent the General Court took into consideration, in a legally correct manner, all the essential factors to assess the gravity of particular conduct in the light of Article 101 TFEU and Article 23 of Regulation No 1/2003, and, secondly, to consider whether the General Court responded to a sufficient legal standard to all the arguments raised in support of the claim for cancellation or reduction of the fine. (143)

243. Furthermore, it is not for the Court of Justice, when ruling on questions of law in the context of an appeal, to substitute, on grounds of fairness, its own assessment for that of the General Court exercising its unlimited jurisdiction to rule on the amount of fines imposed on undertakings. Accordingly, only inasmuch as the Court of Justice considers that the level of the penalty is not merely inappropriate, but also excessive to the point of being disproportionate, would it have to find that the General Court erred in law. (144)

244. In the present case, it is apparent from paragraphs 796 to 811 of the judgment under appeal that the General Court correctly took account of all the essential factors when it assessed the gravity of the infringements in question — namely the nature of restrictions of competition by object, the wide geographic scope and the implementation of those infringements, as well as Lundbeck's significant market share — and that it also responded to a sufficient standard to the opposing arguments raised by the appellants, which, moreover, the appellants do not dispute.

245. Furthermore, in the light of the factors thus taken into account, the gravity percentages applied by the Commission in this case and endorsed by the General Court do not appear to be disproportionate, particularly since, as the General Court correctly found in paragraph 806 of the judgment under appeal, those percentages are at the lower end of the scale provided for in paragraph 21 of the 2006 Guidelines.

246. The arguments put forward by the appellants in the present appeal are not capable of calling those considerations into question.

247. Thus, the appellants claim that, by endorsing the gravity percentages set by the Commission, the General Court failed to take proper account of the geographic scope of the infringements in question, since that scope was limited due to the fact that some of the markets of the EEA Member States were actually closed to the generic manufacturers during the term of the agreements at issue. However, it follows from the examination of the first part of this ground of appeal that the premisses on which that line of argument is based are incorrect. (145)

248. The appellants also maintain that a significantly lower gravity percentage should have been applied because the infringements in question did not meet the definition of 'cartels'. However, it is apparent from

the considerations set out above that those infringements consisted of agreements the purpose of which was to pay competitors to stay out of the market and that Lundbeck could not have been unaware of the anticompetitive nature of such action. (146) Therefore, irrespective of what the appellants mean by 'the definition of cartels', it is not clear why a lower gravity percentage should have been set for that type of conduct.

249. It follows from these considerations that the second part of the sixth ground of appeal must also be rejected, as must, therefore, this ground of appeal in its entirety.

C. Conclusion

250. As none of the grounds of appeal put forward by the appellants has been successful, the appeal must be dismissed in its entirety.

V. Costs

251. Under Article 184(2) of its Rules of Procedure, the Court is to make a decision as to costs where it dismisses an appeal.

252. First, under Article 138(1) and (2) of the Rules of Procedure, which applies to appeal proceedings by virtue of Article 184(1) thereof, the unsuccessful party is to be ordered to pay the costs if they have been applied for in the successful party's pleadings; where there is more than one unsuccessful party, the Court is to decide how the costs are to be shared. Since the Commission has applied for costs and the appellants have been unsuccessful in their grounds of appeal, they must be ordered to bear their own costs and to pay those incurred by the Commission. Since they brought the appeal jointly, they must bear the costs jointly and severally.

253. Next, under Article 184(4) of its Rules of Procedure, the Court may decide that an intervener at first instance who has participated in the written or oral part of the proceedings before the Court is to bear its own costs. Since EFPIA participated in the written and oral parts of the present appeal proceedings, it should therefore be ordered to bear its own costs.

254. Lastly, under the combined provisions of Articles 140(1) and 184(1) of the Rules of Procedure, Member States which have intervened in the proceedings are to bear their own costs. Consequently, the United Kingdom must be ordered to bear its own costs.

VI. Conclusion

255. On the basis of the above considerations, I propose that the Court should:

1. Dismiss the appeal;

2. Order H. Lundbeck A/S and Lundbeck Ltd jointly and severally to bear their own costs and to pay those incurred by the European Commission;

3. Order the European Federation of Pharmaceutical Industries and Associations and the United Kingdom of Great Britain and Northern Ireland each to bear their own costs.

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1 Original language: French.

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2 See, to that effect, recitals 9 and 10 of Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use (OJ 2001

L 311, p. 67), and judgments of 3 December 1998, *Generics (UK) and Others* (C-368/96, EU:C:1998:583, paragraph 4), and of 16 October 2003, *AstraZeneca* (C-223/01, EU:C:2003:546, paragraphs 42 and 52); see, also, the judgment of the General Court of 15 September 2015, *Novartis Europharm* v *Commission* (T-472/12, EU:T:2015:637, paragraphs 62 and 63), and my Opinion in *Warner-Lambert Company* (C-423/17, EU:C:2018:822, point 1 et seq.).

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3 Judgments of 31 October 1974, *Centrafarm and de Peijper* (15/74, EU:C:1974:114, paragraph 9); of 18 February 1992, *Commission* v *Italy* (C-235/89, EU:C:1992:73, paragraph 17); of 27 October 1992, *Generics and Harris Pharmaceuticals* (C-191/90, EU:C:1992:407, paragraph 23); and of 5 December 1996, *Merck and Beecham* (C-267/95 and C-268/95, EU:C:1996:468, paragraphs 30 and 31).

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4 Judgment of 25 February 1986, *Windsurfing International* v *Commission* (193/83, EU:C:1986:75, paragraphs 89 and 92).

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5 Judgment of 30 January 2020, *Generics (UK) and Others* (C-307/18, EU:C:2020:52, paragraphs 52 and 81); see, also, my Opinion in *Generics (UK) and Others* (C-307/18, EU:C:2020:28, points 67 to 75).

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6 See recitals 5 and 81 of Commission Decision C(2013) 3803 final of 19 June 2013 relating to a proceeding under Article 101 TFEU and Article 53 of the EEA Agreement (Case AT.39226 — Lundbeck) ('the decision at issue').

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7 Judgment of the General Court of 8 September 2016, *Lundbeck* v *Commission* (T-472/13, EU:T:2016:449) ('the judgment under appeal'). In addition to the judgment under appeal, the decision at issue gave rise to the following judgments of the General Court, also under appeal: of 8 September 2016, *Sun Pharmaceutical Industries and Ranbaxy (UK)* v *Commission* (T-460/13, not published, EU:T:2016:453; Case C-586/16 P, pending); *Arrow Group and Arrow Generics* v *Commission* (T-467/13, not published, EU:T:2016:450; Case C-601/16 P, pending); *Generics (UK)* v *Commission* (T-469/13, not published, EU:T:2016:454; Case C-588/16 P, pending); *Merck* v *Commission* (T-470/13, not published, EU:T:2016:452; Case C-614/16 P, pending); and *Xellia Pharmaceuticals and Alpharma* v *Commission* (T-471/13, not published, EU:T:2016:460; Case C-611/16 P, pending).

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8 C-307/18, EU:C:2020:52.

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9 See Commission Decision C(2014) 4955 final of 9 July 2014 relating to a proceeding under Articles 101 and 102 TFEU (Case AT.39612 — Perindopril (Servier)). That decision gave rise to the following judgments of the General Court, currently under appeal: of 12 December 2018, *Biogaran* v *Commission* (T-677/14, EU:T:2018:910; Case C-207/19 P, pending); *Teva UK and Others* v *Commission* (T-679/14, not published, EU:T:2018:919; Case C-198/19 P, pending); *Lupin* v *Commission* (T-680/14, not published, EU:T:2018:908; Case C-144/19 P, pending); *Mylan Laboratories and Mylan* v *Commission* (T-682/14, not published, EU:T:2018:907; Case C-197/19 P, pending); *Krka* v *Commission* (T-684/14, not published, EU:T:2018:918; Case C-151/19 P, pending); *Servier and Others* v *Commission* (T-691/14, EU:T:2018:922; Cases C-176/19 P and C-201/19 P, pending); *Niche Generics* v *Commission* (T-701/14, not published, EU:T:2018:921; Case C-164/19 P, pending); and *Unichem Laboratories* v *Commission* (T-705/14, not published, EU:T:2018:915; Case C-166/19 P, pending).

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10 Paragraph 1 of the judgment under appeal.

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11 Provided for in Council Regulation (EEC) No 1768/92 of 18 June 1992 concerning the creation of a supplementary protection certificate for medicinal products (OJ 1992 L 182, p. 1), now replaced by Regulation (EC) No 469/2009 of the European Parliament and of the Council of 6 May 2009 concerning the supplementary protection certificate for medicinal products (OJ 2009 L 152, p. 1).

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12 Paragraphs 15 to 17 of the judgment under appeal.

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13 Paragraphs 18 to 21 of the judgment under appeal. The patents in dispute were issued by the EPO in 2001 (amide) and 2003 (iodo), respectively, and in several Member States and by the EPO in 2002 (crystallisation). The patent for the production of citalopram by film distillation was issued in the United Kingdom in 2001 and revoked in 2004, and a similar patent was issued in Denmark in 2002.

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14 Paragraph 22 of the judgment under appeal.

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15 Paragraphs 3, 4 and 25 to 29 of the judgment under appeal.

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16 Paragraphs 30 and 31 of the judgment under appeal.

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17 Paragraphs 5 to 8 and 33 to 36 of the judgment under appeal.

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18 Paragraphs 37 to 39 of the judgment under appeal.

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19 Paragraphs 9 to 11 and 40 to 45 of the judgment under appeal.

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20 Paragraphs 12 to 14 and 46 to 48 of the judgment under appeal.

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21 Paragraphs 71 and 75 of the judgment under appeal.

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22 See footnote 7 above.

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23 C-591/16 P, not published, EU:C:2016:967.

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24 C-591/16 P, not published, EU:C:2017:532.

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25 See footnote 7 above.

26 C-307/18, EU:C:2020:52.

27 See, to that effect, judgment of 30 January 2020, *Generics (UK) and Others* (C-307/18, EU:C:2020:52, paragraphs 30 to 32), and my Opinion in *Generics (UK) and Others* (C-307/18, EU:C:2020:28, point 57 and the case-law cited).

28 See paragraph 127 of the judgment under appeal and, as regards the respective dates when the patents were granted and when the agreements at issue were concluded, points 9 and 11 to 17 above.

29 See paragraphs 120 to 122, 128, 130 and 132 of the judgment under appeal.

30 Judgments of 20 January 2016, *Toshiba Corporation* v *Commission* (C-373/14 P, EU:C:2016:26, paragraphs 31, 32 and 34), and of 30 January 2020, *Generics (UK) and Others* (C-307/18, EU:C:2020:52, paragraph 45); see, also, judgments of the General Court of 28 June 2016, *Portugal Telecom* v *Commission* (T-208/13, EU:T:2016:368, paragraph 181), and *Telefónica* v *Commission* (T-216/13, EU:T:2016:369, paragraph 221).

31 Judgment of 30 January 2020, *Generics (UK) and Others* (C-307/18, EU:C:2020:52, paragraphs 36 and 37); see, also, to that effect, judgment of 28 February 1991, *Delimitis* (C-234/89, EU:C:1991:91, paragraph 21). As regards the conditions under which the Commission can categorise an undertaking as a potential competitor, see judgments of the General Court of 15 September 1998, *European Night Services and Others* v *Commission* (T-374/94, T-375/94, T-384/94 and T-388/94, EU:T:1998:198, paragraph 137); of 14 April 2011, *Visa Europe and Visa International Service* v *Commission* (T-461/07, EU:T:2011:181, paragraphs 68, 166 and 167); and of 29 June 2012, *E.ON Ruhrgas and E.ON* v *Commission* (T-360/09, EU:T:2012:332, paragraphs 85 and 86). See, also, paragraph 10 of the Commission's Guidelines on the applicability of Article 101 TFEU to horizontal cooperation agreements (OJ 2011 C 11, p. 1).

32 Judgment of 30 January 2020, *Generics (UK) and Others* (C-307/18, EU:C:2020:52, paragraphs 34 and 46).

33 Judgment of 30 January 2020, *Generics (UK) and Others* (C-307/18, EU:C:2020:52, paragraph 48).

34 Judgment of the General Court of 1 July 2010, *AstraZeneca* v *Commission* (T-321/05, EU:T:2010:266, paragraph 362).

35 See paragraph 121 of the judgment under appeal; see, also, judgment of the General Court of 12 December 2018, *Servier and Others* v *Commission* (T-691/14, EU:T:2018:922, paragraph 359).

36 See, in that regard, my Opinion in *Generics (UK) and Others* (C-307/18, EU:C:2020:28, point 67).

37 Judgment of 30 January 2020, *Generics (UK) and Others* (C-307/18, EU:C:2020:52, paragraphs 52 and 81); see, also, my Opinion in *Generics (UK) and Others* (C-307/18, EU:C:2020:28, points 73 and 74).

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38 See paragraphs 117, 119, 390 and 487 of the judgment under appeal.

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39 Judgments of 31 October 1974, *Centrafarm and de Peijper* (15/74, EU:C:1974:114, paragraph 9); of 18 February 1992, *Commission* v *Italy* (C-235/89, EU:C:1992:73, paragraph 17); of 27 October 1992, *Generics and Harris Pharmaceuticals* (C-191/90, EU:C:1992:407, paragraph 23); and of 5 December 1996, *Merck and Beecham* (C-267/95 and C-268/95, EU:C:1996:468, paragraphs 30 and 31).

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40 Judgment of 25 February 1986, *Windsurfing International* v *Commission* (193/83, EU:C:1986:75, paragraphs 89 and 92).

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41 See, in that regard, my Opinion in *Warner-Lambert Company* (C-423/17, EU:C:2018:822, point 57).

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42 See paragraphs 124 to 129 of the judgment under appeal.

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43 See, in that regard, my Opinion in *Generics (UK) and Others* (C-307/18, EU:C:2020:28, points 40 to 42 and 72).

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44 See, in that regard, my Opinion in *Generics (UK) and Others* (C-307/18, EU:C:2020:28, point 125).

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45 Judgment of 30 January 2020, *Generics (UK) and Others* (C-307/18, EU:C:2020:52, paragraph 50); see, also, my Opinion in *Generics (UK) and Others* (C-307/18, EU:C:2020:28, point 83).

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46 Judgment of 30 January 2020, *Generics (UK) and Others* (C-307/18, EU:C:2020:52, paragraph 51); see, also, my Opinion in *Generics (UK) and Others* (C-307/18, EU:C:2020:28, points 84 and 85).

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47 See judgment of the General Court of 15 September 1998, *European Night Services and Others* v *Commission* (T-374/94, T-375/94, T-384/94 and T-388/94, EU:T:1998:198, paragraph 139), relied on by the appellants, and judgment of the General Court of 29 June 2012, *E.ON Ruhrgas and E.ON* v *Commission* (T-360/09, EU:T:2012:332, paragraph 89).

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48 See paragraph 162 of the judgment under appeal, read in conjunction with paragraphs 120 to 132 thereof.

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49 OJ 2014 C 89, p. 3.

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50 See order of 29 September 2010, *EREF* v *Commission* (C-74/10 P and C-75/10 P, not published, EU:C:2010:557, paragraphs 41 and 42 and the case-law cited).

51 Judgment of 30 January 2020, *Generics (UK) and Others* (C-307/18, EU:C:2020:52, paragraph 44); see, also, my Opinion in *Generics (UK) and Others* (C-307/18, EU:C:2020:28, point 88).

52 Judgment of 30 January 2020, *Generics (UK) and Others* (C-307/18, EU:C:2020:52, paragraph 54 et seq.); see, also, my Opinion in *Generics (UK) and Others* (C-307/18, EU:C:2020:28, points 86 and 87).

53 Judgment of 30 January 2020, *Generics (UK) and Others* (C-307/18, EU:C:2020:52, paragraphs 42, 56 and 57); see, also, judgments of the General Court of 14 April 2011, *Visa Europe and Visa International Service* v *Commission* (T-461/07, EU:T:2011:181, paragraph 169), and of 12 December 2018, *Servier and Others* v *Commission* (T-691/14, EU:T:2018:922, paragraph 342 et seq.), and my Opinion in *Generics (UK) and Others* (C-307/18, EU:C:2020:28, points 60, 86, 87 and 94).

54 See, to that effect, judgment of 21 January 2016, *Galp Energía España and Others* v *Commission* (C-603/13 P, EU:C:2016:38, paragraph 72).

55 Judgments of 25 January 2007, *Dalmine* v *Commission* (C-407/04 P, EU:C:2007:53, paragraphs 49 and 63), and of 27 April 2017, *FSL and Others* v *Commission* (C-469/15 P, EU:C:2017:308, paragraph 38); see, also, my Opinion in *FSL and Others* v *Commission* (C-469/15 P, EU:C:2016:884, point 30 et seq.).

56 Order of 12 June 2019, *OY* v *Commission* (C-816/18 P, not published, EU:C:2019:486, paragraph 4 (6)), and judgments of the General Court of 15 March 2000, *Cimenteries CBR and Others* v *Commission* (T-25/95, T-26/95, T-30/95 to T-32/95, T-34/95 to T-39/95, T-42/95 to T-46/95, T-48/95, T-50/95 to T-65/95, T-68/95 to T-71/95, T-87/95, T-88/95, T-103/95 and T-104/95, EU:T:2000:77, paragraph 1053); of 16 June 2015, *FSL and Others* v *Commission* (T-655/11, EU:T:2015:383, paragraph 183); and of 14 March 2018, *Kim and Others* v *Council and Commission* (T-533/15 and T-264/16, EU:T:2018:138, paragraph 224).

57 See, in particular, paragraphs 122 and 126 of the judgment under appeal and recitals 149 and 157 and footnotes 292 and 322 of the decision at issue.

58 See, to that effect, judgments of the General Court of 27 September 2006, *Archer Daniels Midland* v *Commission* (T-59/02, EU:T:2006:272, paragraph 277); of 8 July 2008, *Lafarge* v *Commission* (T-54/03, not published, EU:T:2008:255, paragraph 379); of 11 July 2014, *Esso and Others* v *Commission* (T-540/08, EU:T:2014:630, paragraph 75); and of 16 June 2015, *FSL and Others* v *Commission* (T-655/11, EU:T:2015:383, paragraph 208).

59 Judgment of 30 January 2020, *Generics (UK) and Others* (C-307/18, EU:C:2020:52, paragraph 53); see, also, in that regard, my Opinion in *Generics (UK) and Others* (C-307/18, EU:C:2020:28, points 89 to 93).

60 See points 44 to 64 of this Opinion above, especially points 55 to 58.

61 See points 86 to 93 of this Opinion above.

62 See, in particular, paragraph 171 of the judgment under appeal.

63 See paragraphs 313 and 314 of the judgment under appeal.

64 See footnote 2 above.

65 See paragraph 179 of the judgment under appeal and, specifically as regards Merck (GUK), paragraphs 172, 230 and 231 of the judgment under appeal; as regards Arrow, paragraphs 173, 174, 246, 249 and 269 of the judgment under appeal; as regards Alpharma, paragraphs 175, 176 and 290 of the judgment under appeal; and, as regards Ranbaxy, paragraphs 177, 178 and 312 to 326 of the judgment under appeal.

66 Judgment of 30 January 2020 (C-307/18, EU:C:2020:52).

67 See point 33 of this Opinion above.

68 Judgment of 30 January 2020 (C-307/18, EU:C:2020:52).

69 See, in particular, paragraph 335 of the judgment under appeal.

70 See, in particular, paragraphs 352, 358 to 360, 363, 369, 401, 412, 414, 425, 428, 431 and 490 of the judgment under appeal.

71 See paragraphs 478 to 500 of the judgment under appeal, especially paragraphs 491 and 495.

72 Judgment of 30 January 2020 (C-307/18, EU:C:2020:52).

73 Judgment of 30 January 2020, *Generics (UK) and Others* (C-307/18, EU:C:2020:52, paragraphs 78, 81, 83 to 89, 92, 93, 97, 100 and 102); see, also, my Opinion in *Generics (UK) and Others* (C-307/18, EU:C:2020:28, points 108 to 120 and 130 to 140).

74 Judgment of 30 January 2020, *Generics (UK) and Others* (C-307/18, EU:C:2020:52, paragraphs 85 to 95).

75 See, in particular, paragraphs 361, 363, 414, 430 and 431 of the judgment under appeal.

76 Judgments of 7 February 2013, *Slovenská sporiteľňa* (C-68/12, EU:C:2013:71, paragraph 20), and of 30 January 2020, *Generics (UK) and Others* (C-307/18, EU:C:2020:52, paragraph 88).

77 See, to that effect, paragraph 387 of the judgment under appeal and the judgment of the General Court of 27 July 2005, *Brasserie nationale and Others* v *Commission* (T-49/02 to T-51/02, EU:T:2005:298, paragraph 81).

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78 Judgment of 30 January 2020 (C-307/18, EU:C:2020:52).

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79 See point 33 of this Opinion above.

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80 See points 66 to 113 of this Opinion above (consideration of the fourth ground of appeal, relating to the existence of potential competition between Lundbeck and the generic manufacturers).

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81 Judgment of 30 January 2020 (C-307/18, EU:C:2020:52, paragraph 100).

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82 See, in that regard, my Opinion in *Generics (UK) and Others* (C-307/18, EU:C:2020:28, points 121 to 129).

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83 See, in particular, paragraphs 363, 369, 390, 401, 429 and 474 of the judgment under appeal.

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84 Judgment of 30 January 2020 (C-307/18, EU:C:2020:52).

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85 See point 33 of this Opinion above.

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86 Although the referring court in *Generics (UK) and Others* assumed that the agreements at issue in that case prohibited the generic manufacturers concerned from pursuing their actions challenging the patent in dispute during the agreed period, it is not clear that those agreements contained explicit no-challenge clauses applying to that patent (see paragraphs 13, 14 and 21 of the Court's judgment in the case of 30 January 2020, C-307/18, EU:C:2020:52).

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87 See paragraphs 23 to 48 of the judgment under appeal.

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88 See, in that regard, in particular, points 49 to 58 and 140 of this Opinion above.

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89 See, in that regard, specifically concerning the agreement between Lundbeck and Merck (GUK) for the United Kingdom, paragraphs 574 to 576 of the judgment under appeal.

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90 See paragraphs 427, 486 to 488, 498, 769 and 770 of the judgment under appeal.

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91 Judgments of 27 September 1988, *Bayer and Maschinenfabrik Hennecke* (65/86, EU:C:1988:448, paragraphs 14 to 16), and of 30 January 2020, *Generics (UK) and Others* (C-307/18, EU:C:2020:52, paragraph 80); see, also, my Opinion in *Generics (UK) and Others* (C-307/18, EU:C:2020:28, point 133).

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92 Judgments of 13 July 1966, *Consten and Grundig* v *Commission* (56/64 and 58/64, EU:C:1966:41, p. 346); of 18 February 1971, *Sirena* (40/70, EU:C:1971:18, paragraph 9); of 8 June 1982, *Nungesser and Eisele* v *Commission* (258/78, EU:C:1982:211, paragraph 28); of 25 February 1986, *Windsurfing International* v *Commission* (193/83, EU:C:1986:75, paragraph 46); of 27 September 1988, *Bayer and Maschinenfabrik Hennecke* (65/86, EU:C:1988:448, paragraph 16); and of 30 January 2020, *Generics (UK) and Others* (C-307/18, EU:C:2020:52, paragraphs 49, 79, 81 and 82). See, also, my Opinion in *Generics (UK) and Others* (C-307/18, EU:C:2020:28, points 108 to 112).

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93 For an analysis of those judgments, see footnote 84 of my Opinion in *Generics (UK) and Others* (C-307/18, EU:C:2020:28). The judgment of 8 June 1982, *Nungesser and Eisele* v *Commission* (258/78, EU:C:1982:211, paragraphs 56 to 58), also relied on by the appellants and not addressed in that footnote, does not lead to a different conclusion, since it merely confirms that, in the area of plant variety rights, the grant of an exclusive licence may be compatible with what is now Article 101 TFEU in specific circumstances.

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94 See paragraphs 354, 360, 383, 384, 412, 475, 497, 718 and 835 of the judgment under appeal.

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95 See judgment of 11 September 2014, *CB* v *Commission* (C-67/13 P, EU:C:2014:2204, paragraphs 53 and 54 and the case-law cited); see, also, my Opinions in *T-Mobile Netherlands and Others* (C-8/08, EU:C:2009:110, point 38 et seq. and the case-law cited), and in *Generics (UK) and Others* (C-307/18, EU:C:2020:28, point 158), as well as the Opinion of Advocate General Wahl in *CB* v *Commission* (C-67/13 P, EU:C:2014:1958, point 40 et seq. and the case-law cited), and the Opinion of Advocate General Bobek in *Budapest Bank and Others* (C-228/18, EU:C:2019:678, point 46).

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96 See order of 12 March 2020, *EMB Consulting and Others* v *ECB* (C-571/19 P, not published, EU:C:2020:208, paragraph 16 and the case-law cited).

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97 In the course of that examination, the General Court held, in paragraph 569 of the judgment under appeal, that the Commission had not established to the requisite legal standard that the restrictions contained in the agreement between Merck (GUK) and Lundbeck for the United Kingdom (point 12 of this Opinion above and paragraphs 25 to 29 of the judgment under appeal) exceeded the scope of the latter's patents. However, the General Court found, in paragraphs 570 to 577 of the judgment under appeal, that that finding was not capable of affecting the lawfulness of the decision at issue since, in any event, the agreement in question was anticompetitive and Merck (GUK) no longer had any incentive, on account of the provisions of that agreement viewed in their context, to purchase citalopram in the form of API from a third party or to sell citalopram in the form of finished products other than that of Lundbeck, even though it was in principle free to do so under the agreement.

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98 See paragraphs 354, 515, 801 and 840 of the judgment under appeal.

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99 See point 69 of this Opinion above and the case-law cited as well as, concerning the interpretation of the wording of the agreements at issue, judgment of 29 October 2015, *Commission* v *ANKO* (C-78/14 P,

EU:C:2015:732, paragraph 23).

100 See points 132 to 143 and 150 to 157 of this Opinion above.

101 Council Regulation of 16 December 2002 on the implementation of the rules on competition laid down in Articles 81 and 82 of the Treaty (OJ 2003 L 1, p. 1).

102 See judgment of 18 June 2013, *Schenker & Co. and Others* (C-681/11, EU:C:2013:404, paragraphs 37 and 38 and the case-law cited).

103 See, in particular, points 133 and 152 of this Opinion above.

104 See, in particular, paragraph 368 of the judgment under appeal ('the evidence contemporaneous to the agreements at issue shows that the [appellants] intended to use "a large pile of [USD]" to exclude generics from the market') and paragraphs 524, 528 and 839 thereof (finding that factual evidence confirms the existence of a strategy on the part of Lundbeck to delay the market entry of generics, of which the agreements at issue formed part).

105 Judgment of 28 June 2005, *Dansk Rørindustri and Others* v *Commission* (C-189/02 P, C-202/02 P, C-205/02 P to C-208/02 P and C-213/02 P, EU:C:2005:408, paragraphs 217 and 218).

106 See points 182 and 184 of this Opinion above.

107 See point 133 of this Opinion above.

108 See point 152 of this Opinion above.

109 See points 156 and 157 of this Opinion above.

110 See judgment of 28 June 2005, *Dansk Rørindustri and Others* v *Commission* (C-189/02 P, C-202/02 P, C-205/02 P to C-208/02 P and C-213/02 P, EU:C:2005:408, paragraph 219), also cited in paragraph 767 of the judgment under appeal.

111 See the case-law cited in point 176 of this Opinion above.

112 See point 157 of this Opinion above.

113 Recitals 1316 to 1358 of the decision at issue.

114 OJ 2006 C 210, p. 2.

115 See point 19 of this Opinion above.

116 See, as regards the geographic scope of each of the agreements at issue, points 12 to 17 of this Opinion above.

117 Emphasis added.

118 See judgments of 11 July 2013, *Team Relocations and Others* v *Commission* (C-444/11 P, not published, EU:C:2013:464, paragraph 76); of 12 November 2014, *Guardian Industries and Guardian Europe* v *Commission* (C-580/12 P, EU:C:2014:2363, paragraph 57); of 19 March 2015, *Dole Food and Dole Fresh Fruit Europe* v *Commission* (C-286/13 P, EU:C:2015:184, paragraph 148); of 23 April 2015, *LG Display and LG Display Taiwan* v *Commission* (C-227/14 P, EU:C:2015:258, paragraph 53); and of 7 September 2016, *Pilkington Group and Others* v *Commission* (C-101/15 P, EU:C:2016:631, paragraph 19). See, also, my Opinion in *Pilkington Group and Others* v *Commission* (C-101/15 P, EU:C:2016:258, points 26 and 31 to 33).

119 See, to that effect, judgments of 11 July 2013, *Team Relocations and Others* v *Commission* (C-444/11 P, not published, EU:C:2013:464, paragraph 77); of 12 November 2014, *Guardian Industries and Guardian Europe* v *Commission* (C-580/12 P, EU:C:2014:2363, paragraph 58); and of 9 July 2015, *InnoLux* v *Commission* (C-231/14 P, EU:C:2015:451, paragraph 62). See, also, my Opinion in *Pilkington Group and Others* v *Commission* (C-101/15 P, EU:C:2016:258, point 34).

120 See, to that effect, judgment of 7 September 2016, *Pilkington Group and Others* v *Commission* (C-101/15 P, EU:C:2016:631, paragraph 22), and my Opinion in *Pilkington Group and Others* v *Commission* (C-101/15 P, EU:C:2016:258, point 35).

121 See point 133 of this Opinion above.

122 See, in particular, points 140 and 141 of this Opinion above.

123 See points 101 to 112 of this Opinion above.

124 In recital 109 of the decision at issue, the Commission stated that, in Austria, the protection afforded by the original patent covered only the original processes for producing the citalopram compound, not the compound itself, so that generic manufacturers could, in principle, have entered the market as soon as the regulatory data protection period had expired (see, concerning the legal framework in that regard, judgment of 28 June 2017, *Novartis Europharm* v *Commission*, C-629/15 P and C-630/15 P, EU:C:2017:498, paragraph 2 et seq.) if they had identified another industrially exploitable manufacturing process. However, in recitals 111 and 827 and footnote 1124 of the decision at issue, the Commission refers to the protection of the compound in Austria and, in general, it appears that the Commission took as its starting point the principle that the protection

of the original patent did not expire in Austria until 2003 (see, in particular, footnote 644 of the decision at issue).

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125 See, in that regard, paragraph 163 of the judgment under appeal and judgments of 6 December 2012, *AstraZeneca* v *Commission* (C-457/10 P, EU:C:2012:770, paragraph 108), and of 30 January 2020, *Generics (UK) and Others* (C-307/18, EU:C:2020:52, paragraph 51). See, also, my Opinion in *Generics (UK) and Others* (C-307/18, EU:C:2020:28, points 76 and 84).

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126 See, concerning this criterion for determining whether there is potential competition notwithstanding the existence of a patent, point 59 of this Opinion above. As regards the obtaining of MAs in Austria by the generic manufacturers, see paragraphs 176 and 227 of the judgment under appeal.

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127 See the case-law cited in points 217 to 219 of this Opinion above.

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128 See, in that regard, my Opinion in *Pilkington Group and Others* v *Commission* (C-101/15 P, EU:C:2016:258, point 36).

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129 Paragraph 171 of the judgment under appeal.

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130 See, in that regard, recital 171 of the decision at issue.

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131 Judgment of 29 June 2012 (T-360/09, EU:T:2012:332).

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132 Judgment of 28 June 2016 (T-216/13, EU:T:2016:369).

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133 See judgment of 29 June 2012, *E.ON Ruhrgas and E.ON* v *Commission* (T-360/09, EU:T:2012:332, paragraph 88 et seq.).

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134 Judgment of 29 June 2012, *E.ON Ruhrgas and E.ON* v *Commission* (T-360/09, EU:T:2012:332, paragraphs 90 to 93).

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135 See paragraph 223 of this Opinion above.

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136 See judgment of 28 June 2016, *Telefónica* v *Commission* (T-216/13, EU:T:2016:369, paragraph 290 et seq.).

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137 See points 37 to 113 of this Opinion above (consideration of the appellants' fourth ground of appeal alleging that there was no potential competition between Lundbeck and the generic manufacturers).

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138 The appellants rely in that regard on paragraph 31 of the judgment of 4 June 2009, *T-Mobile Netherlands and Others* (C-8/08, EU:C:2009:343).

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139 See paragraphs 399 and 805 of the judgment under appeal.

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140 See point 133 of this Opinion above. See, also, in that regard, my Opinion in *Generics (UK) and Others* (C-307/18, EU:C:2020:28, points 196 to 199).

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141 Recitals 1331 and 1332 of the decision at issue.

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142 See points 12 to 17 of this Opinion above.

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143 Judgments of 17 December 1998, *Baustahlgewebe* v *Commission* (C-185/95 P, EU:C:1998:608, paragraph 128); of 28 June 2005, *Dansk Rørindustri and Others* v *Commission* (C-189/02 P, C-202/02 P, C-205/02 P to C-208/02 P and C-213/02 P, EU:C:2005:408, paragraph 244); and of 26 September 2018, *Infineon Technologies* v *Commission* (C-99/17 P, EU:C:2018:773, paragraph 192).

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144 Judgments of 17 December 1998, *Baustahlgewebe* v *Commission* (C-185/95 P, EU:C:1998:608, paragraph 129); of 28 June 2005, *Dansk Rørindustri and Others* v *Commission* (C-189/02 P, C-202/02 P, C-205/02 P to C-208/02 P and C-213/02 P, EU:C:2005:408, paragraph 245); of 30 May 2013, *Quinn Barlo and Others* v *Commission* (C-70/12 P, not published, EU:C:2013:351, paragraph 57); and of 26 January 2017, *Villeroy & Boch Austria* v *Commission* (C-626/13 P, EU:C:2017:54, paragraph 86).

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145 See, in particular, points 211, 212, 222, 223, 228, 233 and 234 of this Opinion above.

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146 See points 133, 181 to 190 and 196 to 202 of this Opinion above.