Neutral citation [2021] CAT 9

IN THE COMPETITION APPEAL TRIBUNAL

Case Nos: 1251-1255/1/12/16

Salisbury Square House
8 Salisbury Square
London EC4 8AP

10 May 2021

Before:

THE HON. MR JUSTICE ROTH
(President)
HODGE MALEK QC
DERMOT GLYNN

Sitting as a Tribunal in England and Wales

BETWEEN:

GENERICS (UK) LIMITED
GLAXOSMITHKLINE PLC
(1) XELLIA PHARMACEUTICALS APS (2) ALPHARMA LLC
ACTAVIS UK LIMITED
MERCK KGAA

Appellants

- v -

COMPETITION AND MARKETS AUTHORITY

Respondent

SUPPLEMENTARY JUDGMENT

REPRESENTATION

Mr Stephen Kon and Mr Christophe Humpe (of Macfarlanes LLP) on behalf of Generics (UK) Limited.

Mr James Flynn QC and Mr David Scannell QC (instructed by CMS Cameron McKenna Nabarro Olswang LLP) on behalf of GlaxoSmithKline PLC.

Mr Robert O'Donoghue QC (instructed by Clifford Chance LLP) on behalf of Xellia Pharmaceuticals APS and Alpharma LLC.

Ms Sarah Ford QC (instructed by Macfarlanes LLP) on behalf of Actavis UK Limited.

Ms Ronit Kreisberger QC (instructed by DLA Piper UK LLP) on behalf of Merck KGaA Limited.

Mr Jon Turner QC, Ms Marie Demetriou QC and Mr David Bailey (instructed by CMA Legal) appeared on behalf of the Competition and Markets Authority.

A. INTRODUCTION

1. On 8 March 2018, the Tribunal handed down its judgment ("the CAT Judgment") on the five appeals brought by addressees of the decision of the Competition and Markets Authority of 12 February 2016 ("the Decision") concerning findings of infringements of competition law arising from agreements concerning the pharmaceutical drug, paroxetine. This supplementary judgment uses the same nomenclature and abbreviations as the CAT Judgment and it is to be read alongside the CAT Judgment.

2. By the CAT Judgment, certain grounds in the appeals were dismissed but in respect of others the Tribunal decided to make a reference to the Court of Justice of the European Union ("CJEU") under Art 267 TFEU. Further, the Tribunal decided that as regards the grounds of the appeals challenging the penalties, it would be inappropriate to determine those grounds until after the judgment of the CJEU.

3. The reference comprised ten questions, which are set out in Appendix 1 to this judgment. The reference was received by the CJEU on 7 May 2018. Advocate General Kokott delivered her opinion on 22 January 2020 ("the AG Opinion"). After an unusually brief interval following the AG Opinion, the CJEU issued its judgment on 30 January 2020: Case C-307/18 *Generics (UK) Ltd v Competition and Markets Authority*, EU:C:2020:52 ("the CJ Judgment"). It appears that the CJEU was determined to issue its judgment before the United Kingdom formally ceased to be a member of the European Union on 31 January 2020.

4. The Appellants all filed full written submissions on the implications of the CJ Judgment[1] on about 22 April 2020 and with a delay caused by the Covid-19 pandemic the CMA filed its written submissions in response on 5 June 2020. Those submissions are referred to for convenience as "GSK Sub., Merck Sub., CMA Sub., etc). The parties' various submissions concern both the implications

[1] The Tribunal remains bound by the CJ Judgment as regards EU competition law and in the determination of questions arising under Part I of the CA, pursuant to s. 60A CA, subject to s. 60A(7), None of the parties suggested that any of the considerations in s. 60A(7) meant that it is appropriate to act otherwise.

of the CJ Judgment and their case on penalties. As regards the former, the Appellants all contend that the CJ Judgment supports their appeals whereas the CMA contends that it does the opposite. As regards the latter, the parties' submissions are to be read alongside their original submissions on penalty, which we have re-read. None of the parties sought to make further oral submissions to the Tribunal.

5. It will be necessary to refer to the CJ Judgment in considerable detail. However, it is worth noting at the outset that underlying many of the questions referred was the fact that the agreements at issue settled patent litigation between GSK and, respectively, GUK and Alpharma, and avoided likely patent litigation with IVAX, the outcome of which in each case was uncertain. In other words, the CMA did not determine, nor was it possible for the Tribunal to reach a view, whether or not GSK was likely to have won its claims that the paroxetine product with which the various generic suppliers wished to enter the UK market infringed its patents or, conversely, whether or not the potential generic defendant would have succeeded in showing that the patent was invalid.

6. On that point, the CJ Judgment makes clear that it is not necessary for the purpose of analysis of such agreements under competition law to make an assessment of the strength of the patent or the likely outcome of the patent litigation which was settled or avoided: para. 50, following the AG Opinion, para 83.

7. Against that background, we turn to the outstanding grounds of appeal and the implications for those grounds of the CJ Judgment.

B. WERE GUK AND ALPHARMA POTENTIAL COMPETITORS OF GSK IN THE SUPPLY OF PAROXETINE IN THE UK?

8. The Appellants all challenged the finding in the Decision that GUK and Alpharma were potential competitors of GSK in the supply of paroxetine in the UK. The CAT Judgment made a number of factual findings in that regard, but the legal issues raised were the basis of questions (1)-(2) referred to the CJEU.

The CJ Judgment

9. The CJ Judgment states at para 34:

> "By those questions, the referring court seeks, in essence, to ascertain whether Article 101(1) TFEU must be interpreted as meaning that a manufacturer of an originator medicine who is the holder of a manufacturing process patent for an active ingredient which is in the public domain, on the one hand, and manufacturers of generic medicines who are taking steps to enter the market of the medicine containing that active ingredient, on the other, where those parties are in dispute as to whether that patent is valid or whether the generic medicines concerned infringe that patent, are in potential competition with each other. The referring court also seeks to ascertain whether the existence of court proceedings relating to the validity of the patent concerned, which are still pending and which have given rise to an application for interim relief and the granting of interim measures, and the fact that the patent holder may perceive the manufacturers of generic medicines to be potential competitors, constitute factors that may influence the response to that question."

10. After noting in para 35 that in this case only potential not actual competition is involved, the CJ Judgment proceeds to consider the issues at paras 36-57, leading to the conclusion at para 58, repeated at para (1) of the operative part of the judgment that:

> "… the answer to Questions 1 and 2 is that Article 101(1) TFEU must be interpreted as meaning that a manufacturer of originator medicines who is the holder of a manufacturing process patent for an active ingredient that is in the public domain, on the one hand, and the manufacturers of generic medicines who are preparing to enter the market of the medicine containing that active ingredient, on the other, who are in dispute as to whether that patent is valid or whether the generic medicines concerned infringe that patent, are potential competitors, where it is established that the manufacturer of generic medicines has in fact a firm intention and an inherent ability to enter the market, and that market entry does not meet barriers to entry that are insurmountable, which it is for the referring court to assess."

11. Accordingly, if a generic company enters into an agreement of the kind involved in these proceedings with an originator, the CJEU set out two conditions for the generic company to be regarded as a potential competitor of the originator:

(a) the generic company has a firm intention and inherent ability to enter the market; and

(b) such entry does not face insurmountable barriers to entry.

What is required to satisfy each of these conditions is explained in the CJ Judgment.

12. As regards the first condition, the CJEU states, at para 43, that it is necessary to determine:

> "whether, at the time when that agreement was concluded, the manufacturer concerned of generic medicines had 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 manufacturer of originator medicines."

13. The CJEU proceeds, at para 44, to state that such steps might "include":

(1) measures taken to have, within such a period, the necessary marketing authorisations and an adequate stock of generic medicine, either through its own productions or through supply from third parties;

(2) legal steps undertaken to challenge the originator's patents;

(3) the range of marketing initiatives taken by the generic company to market its product.

14. The CJ Judgment further states, at paras 54-57, that satisfaction of this condition can be confirmed by additional factors, as follows:

> "55. … the conclusion of an agreement between a number of undertakings, operating at the same level in the production chain, some of which had no presence in the market concerned, constitutes a strong indication that a competitive relationship existed between those undertakings [citation omitted]
>
> 56. A further such indication is the intention, made known by a manufacturer of originator medicines and acted upon, to make transfers of value to a manufacturer of generic medicines in exchange for the postponement of the latter's market entry, even though the former claims that such entry would infringe one or more of its process patents. The greater the transfer of value, the stronger the indication.
>
> 57 That intention discloses the perception of the manufacturer of originator medicines of the risk that the manufacturer concerned of generic medicines presents to its commercial interests, that perception being relevant to the assessment of the existence of potential competition, ... where that perception affects the conduct on the market of the manufacturer of originator medicines."

15. As regards the second condition, the CJ Judgment states, at para 46:

> "... the existence of a patent which protects the manufacturing process of an active ingredient that is in the public domain cannot, as such, be regarded as an insurmountable barrier, and does not mean that a manufacturer of generic medicines 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 originator medicines concerned."

16. The CJEU proceeds, at paras 47-53, to reject the arguments advanced by the Appellants based on the presumption of patent validity, the uncertain outcome of the patent dispute, and the existence of interim injunctions. As regards the first of those arguments, the CJEU states, at para 51:

> "..., account must be taken of, inter alia, the following: that the uncertainty as to the validity of patents covering medicines is a fundamental characteristic of the pharmaceutical sector; that the presumption of validity of a patent for an originator medicine does not amount to a presumption that a generic version of that medicine properly placed on the market is illegal; that a patent does not guarantee protection against actions seeking to contest its validity; that such actions, and, in particular, the 'at risk' launch of a generic medicine, and the consequent court proceedings, commonly take place in the period before or immediately after the market entry of such a generic medicine; that, to obtain an MA for a generic medicine, there is no requirement to prove that that marketing does not infringe any originator medicine patent rights; and that, in the pharmaceutical sector, potential competition may be exerted before the expiry of a compound patent protecting an originator medicine, since the manufacturers of generic medicines want to be ready to enter the market as soon as that patent expires.

17. As regards the second of those arguments, the CJEU notably states, at para 52:

> "... the argument that there is a genuine dispute, the outcome of which is uncertain, between the manufacturer of the originator medicine and a manufacturer of the generic version of that medicine who seeks to obtain access to the market for that medicine, the genuineness of their dispute, particularly when it is the subject of court proceedings, far from precluding the existence of any competition between them, rather constitutes evidence of the existence of a potential competitive relationship between them."

See also para 100, where the CJEU states:

> "It is precisely the uncertainty as to the outcome of the court proceedings in relation to whether the patent held by the manufacturer of the originator medicine is valid and whether the generic version of that medicine infringes that patent which contributes, for as long as it lasts, to the existence of a situation of at least potential competition between the two parties to those proceedings."

18. As regards the third of those arguments, the CJEU states, at para 53, that an interim injunction, especially when granted with a cross-undertaking in damages, in no way prejudges the merits of the patent dispute.

Submissions and Discussion

19. GSK alone submits that the CJ Judgment on this aspect of the case has no or only limited application since it is based on the assumption that the originator is relying only on process patents, whereas in fact GSK's Anhydrate and Hemihydrate Patents covered an active substance as well as a manufacturing process.

20. It is not altogether clear why the CJEU reformulated the questions in terms of a process patent: see para 34 of the CJ Judgment quoted at para 9 above. The CJEU expressly referred to the fact that the Anhyhdrate Patent covered product as well as process claims: para 9 of the CJ Judgment. It may be that this was because by the judgment in the BASF trial on 12 July 2002, the Patents Court held that most of the product claims in the Anhydrate Patent were invalid: CAT Judgment at [36]. GSK's claim on the Anhydrate Patent against GUK would have been heard with the BASF action, if the parties had not settled through the GUK Agreement the day before the trial began: CAT Judgment at [32]. The GUK Agreement had a three-year term and thus continued well beyond the judgment in the BASF trial. Moreover, following the judgment in the BASF trial, GSK confined its claim against Alpharma to the process claim in the Anhydrate Patent: CAT Judgment at [37]. And GSK and Alpharma only entered into the Alpharma Agreement several months later, on 12 November 2002. Therefore it seems that the significant claims in the Anhydrate Patent were the process claims, and indeed the CAT Judgment at [49] referred to it as a "process patent".

21. As for the Hemihydrate Patent, as the CAT Judgment pointed out, that did not appear in the end to be a serious issue. GSK abandoned its claim on the Hemihydrate Patent against Alpharma; and never sought to rely on that patent as against Apotex or indeed any of the generic companies which then entered the market after December 2003, although Mr Reilly said in his evidence that if

GSK had thought that the Hemihydrate Patent provided an effective means to stop generic companies entering the market, GSK would have relied on it: CAT Judgment at [202]-[203]. We therefore held that for this case the Anhydrate Patent was the critical patent.[2]

22. In any event, we do not consider that the reasoning in the CJ Judgment is confined to the situation of a process patent. The situation here was that the patent for the API had expired in January 1999: CAT Judgment at [9]. Reading the CJ Judgment as a whole, it seems that the important feature for the CJEU was that the patent for that active ingredient had expired: see e.g. para 134. The relevant patents held by GSK were therefore "secondary" patents: CAT Judgment at [10]. We note that GSK now describes them as closer to "compound patents": GSK Sub, para 3. That indeed is precisely how the CJEU refers to the position: CJ Judgment at para 51.

23. We therefore hold that the two conditions set out by the CJ Judgment are applicable to determine the question of potential competition in this case. We note that this is not challenged by any of the other Appellants.

24. Turning to the application of that test, GUK, Actavis and Xellia/ALLC all rely in particular on the first condition, which they submit was not satisfied on the facts as found by the Tribunal. Merck does not advance any arguments on the potential competition issue in light of the CJ Judgment.

25. GUK submits that it could not be held to have had a "firm intention" to enter the market since its actions that are relied on were taken prior to the interim injunction which GSK obtained on 23 October 2001, whereas the GUK Agreement was entered into on 13 March 2002: GUK Sub, para 2.2.

26. We consider that this amounts to a recycling of the argument in the appeal that we have already dismissed. GUK did not dispute that it had both "the ability

[2] We do not see that the fact that GSK commenced proceedings against GUK on the Hemihydrate Patent, as pointed out in GSK Sub, at fn 5, affects this conclusion. Those proceedings are acknowledged in the CAT Judgment at [98] and [108]. GSK's proceedings against Alpharma also initially relied on the Hemihydrate Patent.

and firm intention" to enter the market if it had not been restrained: CAT Judgment at [96]. Although it sought to argue that its intention changed, or was significantly weakened, by the grant of the interim injunction (and also GSK's separate proceedings based on the Hemihydrate Patent) we rejected that argument on examination of the contemporary evidence: [98]-[113]. GUK pressed on with preparation to contest the trial and it was only the GUK Agreement concluded the day before the trial was due to start which led it to abandon its "firm intention" to launch its own generic product. GUK's satisfaction of the first condition is only confirmed by the additional factors set out in paras 55-57 of the CJ Judgment: para 14 above.

27. GSK, Actavis and Xellia/ALLC contend that Alpharma did not have a "firm intention" to enter the market since the Tribunal found that it was more risk averse than GUK and would not have launched 'at risk' of infringing the product claims in the Anhydrate Patent: CAT Judgment at [117] and [136]. Actavis submits that the BASF judgment and the resulting shift to the process claims in that patent caused "a fundamental change in the merits of independent entry" and that the Tribunal's factual findings on Alpharma's intentions were "only tentative": Actavis Sub, paras 8, 10. Xellia/ALLC refer to the BASF judgment as a "serious setback" for Alpharma that "led to a material change" in its entry plans; they submit that it can be inferred from the CAT Judgment that Alpharma would have entered only if it had prevailed in the litigation: Xellia/ALLC Sub, paras 11-12.

28. We do not accept that the factual findings support that conclusion. The judgment in the BASF revocation proceedings was very helpful to Alpharma since it disposed of the product claims in the Anhydrate Patent which were the claims of greatest concern, although obviously if it had held that the process claims were also invalid that would have removed all uncertainty. Since we found that it was quite clear that Alpharma would not have launched if the product claims had been extant, the statement that Alpharma's intention once it faced only the process claims was "less clear" was simply a relative description as a preface to our discussion of the contemporary evidence. To answer the question of what Alpharma then intended to do was not straightforward because, on 1 August 2002, in response to the indication by the judge in the Patents Court that he

would be prepared to grant an interim injunction Alpharma gave an interim undertaking not to enter. But on our analysis of the evidence, we found that if it had not given this undertaking:

> "then Alpharma probably would have been prepared to launch 'at risk' since it was relatively confident that the BASF/Delta product did not infringe the process claim. Alpharma was thus concerned and frustrated by the prospect of even a relatively short delay." CAT Judgment at [118].

29. The Appellants seize on the word "probably" as indicating something less than a firm intention. But that is to mischaracterise the finding: the adverb simply reflects the fact that this was a finding on the balance of probabilities in an analysis of a hypothetical situation. Alpharma had obtained UK MAs for its product; it had a supplier of the raw ingredient in BASF; and it had entered into contracts for manufacture of the tablets. Even a month after giving its undertaking, Alpharma instructed the manufacturer to proceed with a packing run: CAT Judgment at [121]. Further, while Alpharma did not waive privilege to disclose the advice it received (as to which we draw no adverse inference), its internal documents indicate that it was receiving reports that the process used did not infringe the process claim: CAT Judgment at [120], [122].

30. We should add that we do not consider that the fact that Alpharma approached GSK to discuss settlement rather than the other way round indicates a less firm intention on the part of Alpharma. It is entirely normal for a commercial party to seek to settle court proceedings before trial if it can secure satisfactory terms.

31. The CJ Judgment makes clear that the interim injunction/undertaking should not be regarded as an insuperable barrier to entry, and the fact of the Alpharma Agreement itself, with generous transfers of value to Alpharma, including £0.5 million towards its legal costs (see CAT Judgment at [182]-[183]) can further be relied on to confirm that it satisfies the test laid down for potential competition.

Conclusion

32. Accordingly, we reject the Appellants' arguments under this head and find that GUK and Alpharma were potential competitors of GSK at the time that they entered into, respectively, the GUK and Alpharma Agreements.

C. DID THE GUK AND/OR THE ALPHARMA AGREEMENTS HAVE THE OBJECT OF RESTRICTING COMPETITION?

33. The arguments raised under this head were the basis of questions (3)-(5) referred to the CJEU. The CJ Judgment considers and answers those questions together.

The CJ Judgment

34. The CJEU notes that its prior case-law established that the concept of restriction by object is to be interpreted strictly. It can be applied:

> "only to some concerted practices between undertakings which reveal, in themselves and having regard to the content of their provisions, their objectives, and the economic and legal context of which they form part, a sufficient degree of harm to competition for the view to be taken that it is not necessary to assess their effects, since some forms of coordination between undertakings can be regarded, by their very nature, as being harmful to the proper functioning of normal competition [citations omitted]." (CJ Judgment, para 67).

35. As regards that context, it is established that it is necessary to take account of the nature of the goods affected as well as the real conditions of the functioning and structure of the markets in question. In that regard, the CJ Judgment proceeds to state:

> "69 In this case, the medicines sector not only has strong barriers to entry linked to the conditions attached to the placing of medicines on the market, those conditions being described in paragraphs 40 and 47 of the present judgment, but is also marked, as observed by the referring court with respect to the United Kingdom, by a pricing mechanism that is strictly controlled by legislation and strongly influenced by the market entry of generic medicines. Such entry leads, in the short term, to a very appreciable fall in the sale price of medicines containing an active ingredient that are henceforth sold not only by the manufacturer of the originator medicine, but also by manufacturers of generic medicines.
>
> 70 It follows from all the foregoing, of which the manufacturers of originator medicines and the manufacturers of generic medicines cannot be

> unaware, that the medicines sector is particularly sensitive to a delay in the market entry of the generic version of an originator medicine. Such a delay leads to the maintenance on the market of the medicine concerned of a monopoly price, which is very appreciably higher than the price at which generic versions of that medicine would be sold following their market entry and which has considerable financial consequences, if not for the final consumer, at least for social security authorities."

36. In principle, the charging of a monopoly price for a patented product reflects the intention of the patent legislation, since the incentive which this provides is fundamental to competition on the merits in the market for innovation. If a patent is valid, the charging of such a price for the patented product is therefore not contrary to the consumer interest, and we do not understand the CJEU to suggest otherwise.

37. After summarising the GUK and Alpharma Agreements, the CJEU observed that they were entered into in settlement of genuine patent disputes that were subject to proceedings in the English court. The CJEU held that such a settlement agreement whereby the generic challenger agreed to abandon entry to the market and agreed not to challenge the patent can constitute a restriction by object, but that this is not necessarily the case. The CJ Judgment states:

> "85 The fact that such an agreement involves transfers of value, either pecuniary or non-pecuniary, made by the manufacturer of the originator medicine to the manufacturer of generic medicines is not sufficient ground to classify it as a 'restriction by object', since those transfers of value may prove to be justified, that is, appropriate and strictly necessary having regard to the legitimate objectives of the parties to the agreement.
>
> 86 That may, in particular, be the case where the manufacturer of generic medicines receives from the manufacturer of the originator medicine sums that correspond in fact to compensation for the costs of or disruption caused by the litigation between them, or that correspond to remuneration for the actual supply, immediate or subsequent, of goods or services to the manufacturer of the originator medicines. That may also be the case when the manufacturer of the generic medicines discharges undertakings, particularly financial, given by the patent holder to him, such as a cross-undertaking in damages.
>
> 87 However, such a characterisation as a 'restriction by object' must be adopted when it is plain from the analysis of the settlement agreement concerned that the transfers of value provided for by it cannot have any explanation other than the commercial interest of both the holder of the patent and the party allegedly infringing the patent not to engage in competition on the merits."

38. The CJEU states that this assessment should be approached in three steps:

(1) take into account "all the transfers of value made between the parties, whether those were pecuniary or non-pecuniary", including indirect transfers resulting from profits to be obtained by the generic company from a distribution contract with the originator: paras 90-91;

(2) assess whether the "net gain" arising from the transfers of value by the originator to the generic company may be justified by the existence of any quid pro quo or waivers by the generic company "that are proven and legitimate": para 92; and if it is not,

(3) determine whether that net gain is sufficiently large actually to act as an incentive to the generic company to refrain from entering the market concerned: para 93.

39. As regards the determination at (3), the CJEU explains:

> "In that regard, taking into account the uncertainty as to the outcome of those proceedings, there is no requirement that the transfers of value should necessarily be greater than the profits which the manufacturer of generic medicines would have made if it had been successful in the patent proceedings. All that matters is that those transfers of value are shown to be sufficiently beneficial to encourage the manufacturer of generic medicines to refrain from entering the market concerned and not to compete on the merits with the manufacturer of originator medicines concerned." (CJ Judgment, para 94)

40. If the criterion at (3) is satisfied, the agreement must "in principle" be characterised as an infringement by object: para 95. That conclusion cannot be rebutted on the grounds that (i) the agreement does not exceed the scope or duration of the relevant patent; (ii) the restrictions stemming from such agreements are merely ancillary; or (iii) there is uncertainty as to the validity of the patent, whether that is due to the existence of a genuine patent dispute, pending court proceedings or the grant of an interim injunction preventing entry by the generic company in exchange for a cross-undertaking: paras 96-99. Similarly, uncertainty as to the outcome of the pending proceedings as regards either validity or infringement does not provide a ground to exclude the settlement agreement from being characterised as an infringement by object: para 101.

41. However, where parties rely on the pro-competitive effects of their agreement, those effects must be taken into account, in so far as they are capable of calling into question the overall assessment of whether the agreement reveals a sufficient degree of harm to competition. Any pro-competitive effects must be: (i) demonstrated by evidence, (ii) relevant, (iii) specifically related to the agreement, and (iv) "sufficiently significant so that they justify a reasonable doubt as to whether the agreement causes a sufficient degree of harm to competition": paras 103-106.

Submissions and Discussion

42. GUK submits that the CJ Judgment sets out an entirely different framework for analysis from that in the Decision, with the inference that the CAT Judgment needs reconsideration. We do not accept that. The terms of the CAT Judgment reflect the points taken in the appeals. The legal framework set out in the CAT Judgment at [165] is entirely consistent with the approach of the CJEU. When addressing the terms of the two agreements and the parties' subjective intentions, we specifically addressed the question whether the transfers of value could be understood or justified on a basis other than as payment in return for agreement not to seek independent entry to the market, and examined the various attributions and justifications put forward for the consideration which GSK provided.

43. The Appellants argue that neither the CMA in the Decision nor the CAT Judgment applied the "net gains" test set out by the CJ Judgment: e.g., GSK Sub, para 12.

44. However, the concept of "net gain" is not a term of art. It simply refers to the need to set off any payment or equivalent made by the generic company *to* the originator before assessing the value received by the generic company *from* the originator. We think this is clear from the context in the CJ Judgment, but it is confirmed by the original French text of the judgment which refers to the "*solde positif*" (i.e. positive balance).

45. As regards step 1 of the test, the CMA set out its calculations of the values transferred by each of the two agreements, as repeated in the CAT Judgment at [181]-[182]. Those are appropriately "net figures" since they comprise the distribution "margin": i.e. after allowing for the price at which GUK and Alpharma respectively purchased the products from GSK.

46. We considered those figures and found that the £11.8 million calculated under the Alpharma Agreement was slightly overstated, as explained at [183]. Nonetheless, in each case these constituted very substantial transfers.

47. Some part of the totals could be accounted for by payment for legal costs and the purchase of stock. However, the CMA found that the US$12.5 million attributed to purchase of GUK's stock of paroxetine was significantly above its costs of that production: Decision, para 6.102 (which was not challenged on appeal). Moreover, we found that the very significant sums described in the two agreements as "marketing allowances" were nothing of the sort, and that this was a misleading label for part of the payments: CAT Judgment at [177-180].

48. The Appellants contend that one of the justifications for the transfers was the discharge of GSK's cross-undertakings. However, we considered and rejected this point on the evidence: see the CAT Judgment at [232] as regards GUK; and at [233]-[237] and [241] as regards Alpharma. GUK relies on the consent order for the court proceedings incorporated in the GUK Agreement which provides for discharge of the cross-undertaking as showing that this was a material part of the deal. However, since the court was to discharge the interim injunction obtained by GSK, the cross-undertaking which GSK gave would inevitably have to be discharged as well. An equivalent provision similarly appears in the draft court order attached to the Alpharma Agreement. We consider it significant that although both Agreements attributed the various payments from GSK to particular items, neither Agreement, as the CMA points out, attributes any part of any payment to discharge of liability under the cross-undertaking: indeed, the cross-undertakings are not mentioned at all in the Agreements themselves. It is notable that Dr Reilly, who was involved in the negotiations of both agreements on behalf of GSK, told the CMA that he was not really sure what a cross-undertaking was: CAT Judgment at [223]. In our view, this

highlights the fact that neither GUK nor Alpharma were particularly seeking payment in return for agreement to discharge GSK's undertaking.[3]

49. Merck submits that a "central part" of the assessment whether the net gain was sufficient to serve as an incentive not to proceed with independent market entry should be a profitability analysis (i.e. comparing the anticipated gain from such entry with the net value transfer), which the CMA failed to carry out: Merck Sub, para 9; see also Actavis Sub, para 26. However, the CJEU made clear that in determining whether the net gain is sufficiently large to serve as an incentive to refrain from entry there is no requirement to conduct such an analysis, given the uncertainty over the patent position: CJ Judgment at para 94; see also the AG Opinion at para 120. This also disposes of GSK's apparently more extreme argument that determination of net gains requires calculation whether the generic companies received more under the agreements than their likely profits if GSK "had simply permitted them to enter the market": GSK Sub, para 12.

50. As regards the third step in the analysis, we found that GUK and Alpharma only entered into their settlement agreements with GSK once the value transfers which GSK offered were sufficiently attractive to induce them to give up their attempts to contest the patents and enter the market independently:

> "242. In the light of the totality of the evidence, we therefore conclude that GUK and Alpharma each entered into its respective Agreement not because it feared that it would be likely to lose the pending patent proceedings but because it considered that the terms finally agreed were commercially more advantageous than continuing with the litigation, recognising that there was inevitably a risk that GSK might prevail at trial. The same consideration applied, mutatis mutandis, to Alpharma's decision to extend its Agreement after the first year.
>
> 243. Accordingly, we consider that both the GUK Agreement and the Alpharma Agreement were settlements whereby GSK secured protection for a specified period of its patent position from the risk of entry by a particular generic challenger, in return for transfers to the generic companies of substantial value in both cash and non-cash terms, which was well above any avoided litigation costs."

[3] Although Alpharma had amended a draft of the Agreement to change the attribution of £3 million from compensation for destruction of stock to discharge of GSK's cross-undertaking, that was then amended to ascribe it to "production and preparation costs for launch in the UK market": CAT Judgment at [236]. This figure was in any event less than a third of the total value transferred.

51. Xellia/ALLC seek to rely on the CJEU's formulation that restriction by object requires a significant transfer of value "the sole consideration for which" is the undertaking by the generic company not to enter the market and pursue a patent challenge: CJ Judgment, para 89. They emphasise that, for Alpharma, there were other considerations explaining its non-entry. But the consideration here referred to is consideration flowing from the generic company to GSK. It is the rationale for the originator making the payment that is at issue. The question to be asked is: after allowing for any other justification for any payments made, is there a significant transfer of value from GSK for which there appears to be no consideration for GSK other than the generic company's agreement to give up its attempt to compete?

52. Applying the CJ Judgment, properly understood, we therefore find that each agreement was, "in principle", a restriction by object.

53. GSK, Actavis and Xellia/ALLC submit that the agreements here had pro-competitive benefits which, in accordance with the CJ Judgment, mean that the agreements cannot be characterised as restrictions by object. Although the CJEU dismisses the "pro-competitive effects" as "not only minimal but probably uncertain" (paras 108, 110), that is criticised by the Appellants as (a) inaccurate, and (b) a decision on the facts which is beyond the competence of the CJEU on a preliminary ruling.

54. However, as to accuracy, the CJEU does not say that the "benefits" are uncertain. On the contrary, the CJEU expressly cross-refers to the paragraphs of the AG Opinion which set out the benefits for consumers from the Agreements, as identified by the Tribunal, i.e. a reduction of up to 4% in the average price of paroxetine[4] and improvement in the labelling of packs: CJ Judgment, para 108. The Advocate General, at para 179 of her Opinion, states in terms that those benefits from the Agreements were "certain." But it is appropriate to quote the whole paragraph:

[4] AG Opinion, para 22. The CAT Judgment noted that it was difficult to determine the exact price effect which was the subject of conflicting expert evidence: it was no more than 4% and the mid-point between the adjusted estimates of GSK's and the CMA's experts was about 2.5%: see at [295]-[297].

> "Moreover, as the CAT points out, although the benefits to consumers resulting from the agreements were certain and not potential, they were, nevertheless, paltry compared to the benefits afforded by the subsequent independent entry of generics to the paroxetine market. However, the agreements precisely eliminated the possibility that such entry would take place during the agreed period."

55. The CJEU is not casting doubt on those benefits but stating that the "pro-competitive effects" were not only minimal but probably uncertain. As the CJ Judgment explains at para 109:

> "While the referring court finds that those agreements did in fact give rise to a slight reduction in the price of paroxetine, that court observes at the same time that, as is clear in particular from Question 5(a), the supply of paroxetine by GSK to the manufacturers of generic medicines provided for by those agreements did not give rise to meaningful competitive pressure on GSK. The referring court states on that point that, because of the limited volumes supplied, there being no technical reason for the capping of those volumes, the manufacturers of generic medicines had no interest in competing on prices. Further, in Question 5(b), the referring court alludes to the fact that the agreements concerned brought to consumers some benefits which they would not have had if the holder of the patent had been successful in the proceedings relating to that patent, while observing that those benefits were significantly less than the competitive benefits that would have followed the placing on the market of an independent generic product if the manufacturers concerned of generic medicines had been successful those proceedings. Last, the referring court states that, first, the change in the structure of the market induced by the agreements at issue was due not to the introduction of competition, but to a controlled reorganisation of the market for paroxetine engineered by GSK, and, second, that the supply of paroxetine and the transfer of market share by GSK to the manufacturers of generic medicines should be understood as non-pecuniary transfers of value."[5]

56. We consider that to be a fair summary of this aspect of the CAT Judgment. There is no inaccuracy in the CJEU's approach.

57. As to the CJEU's jurisdictional competence, although factual findings are for the national court, once the CJEU has set out the relevant legal test it is not unusual for it to give guidance to the national court on the application of that test if sufficient facts were set out in the statement of reference and the case file: see Case C-238/05 *Asnef-Equifax* EU:C:2006:734 at para 40. The CJ Judgment follows that approach. In any event, applying the legal test set out by the CJEU and summarised at para 41 above, we find that the benefits here are not so

[5] Neither the CJEU nor the Advocate General refer to the reduction in price to wholesalers. That is unsurprising since the Tribunal found that this should not be regarded as a significant competitive benefit: see at [291].

significant as to create a reasonable doubt as to the anti-competitive object of the Agreements.

Conclusion

58. Accordingly, we dismiss the appeals against the Decision finding that the GUK and Alpharma Agreements were anti-competitive by object.

D. DID THE GUK AND/OR THE ALPHARMA AGREEMENTS HAVE THE EFFECT OF RESTRICTING COMPETITION?

59. All the Appellants challenged the finding by the CMA that the relevant Agreement was a restriction by effect. The arguments under this head gave rise to question (6) referred to the CJEU.

60. Since we are upholding the finding in the Decision of a restriction by object it is strictly unnecessary, as GSK points out, to answer the distinct question of whether there was also a restriction by effect. However, as this was part of the Decision which is the subject of the proceedings and the parties have addressed it, we think it is appropriate to deal with it. GSK, Merck, Actavis and Xellia/ALLC all submit that in the light of the CJ Judgment the Tribunal should set aside the Decision under this head.

The CJ Judgment

61. The CJ Judgment reiterates three established principles involved in determination whether a practice constitutes a restriction by effect, as follows (citations omitted):

> "116 … it is necessary to take into consideration the actual context in which that practice occurs, in particular the economic and legal context in which the undertakings concerned operate, the nature of the goods or services affected, as well as the real conditions of the functioning and the structure of the market or markets in question ….
>
> 117 … the restrictive effects on competition may be both real and potential, but they must, in any event, be sufficiently appreciable.
>
> 118 … competition should be assessed within the actual context in which it would occur in the absence of the agreement in dispute …"

62. Against that background, the CJEU proceeded to address the particular question posed in the reference:

> "119 It follows that, in a situation such as that at issue in the main proceedings, the establishment of the counter-factual does not involve, on the part of the referring court, any definitive finding in relation to the chances of success of the manufacturer of generic medicines in the patent proceedings or to the probability of the conclusion of a less restrictive agreement.
>
> 120 The sole purpose of the counter-factual is to establish the realistic possibilities with respect to that manufacturer's conduct in the absence of the agreement at issue. Accordingly, while that counter-factual cannot be unaffected by the chances of success of the manufacturer of generic medicines in the patent proceedings or again in relation to the probability of conclusion of a less restrictive agreement, those factors constitute, however, only some factors among many to be taken into consideration in order to determine how the market will probably operate and be structured if the agreement concerned is not concluded.
>
> 121 Consequently, in order to establish the existence of appreciable potential or real effects on competition of settlement agreements such as those at issue in the main proceedings, the referring court does not have to find either that the manufacturer of generic medicines who is a party to that agreement would probably[6] have been successful in the patent proceedings, or that the parties to that agreement would probably have concluded a less restrictive settlement agreement."

Submissions and Discussion

63. GSK describes this part of the CJ Judgment as "gnomic", but it does resolve the specific concern that we expressed under this head in the CAT Judgment, i.e. whether the Agreements could be classified as giving rise to a restriction by effect when it was not possible to find on the balance of probabilities either that GUK and/or Alpharma would have been successful in the patent trials that were obviated by their respective Agreements or that in the absence of those Agreements the parties would have come to a less restrictive settlement: CAT Judgment at [333]-[334]. The unequivocal answer by the CJEU is that no such finding is necessary in order to conclude that there was a restriction by effect, and also that no "definitive" finding is needed in relation to the chances of success of either party.

[6] i.e. more than 50% chance: CJ Judgment at para 113.

64. Actavis nonetheless submits that since neither the CMA nor the CAT is able to express a view as to the likelihood either of the generic company succeeding in the patent proceedings or of the conclusion of a less restrictive settlement agreement, "it cannot be concluded that the Alpharma Agreement constituted a restriction of competition by effect": Alpharma Sub, para 33. Merck also criticises the Decision for "failing to take account of GUK's prospects of success at trial: Merck Sub, para 25. And Xellia/ALLC similarly submits that the Decision conflated the *possibility* of potential effects on competition with the need to demonstrate "a sufficiently realistic and probable (potential) effect on competition", which could not be shown given the uncertain outcome of the patent dispute: Xellia/ALLC Sub, para 24.1.

65. However, we think it is necessary to consider the findings of fact set out in the CAT Judgment in light of the guidance in paras 119-120 of the CJ Judgment quoted above. As regards the patent litigation, it is not the case that we were unable to express any view at all as regards the outcome. We could not reach a definitive view on which party to the litigation would have succeeded. However, after reviewing the parties' contemporary documents, expressing their thinking and reactions at the time, we concluded that in the absence of the Agreements the GUK and Alpharma trials would have proceeded and that on the evidence before us it was "equally likely" that the generic companies on the one hand and GSK on the other hand would have won: CAT Judgment at [333]. When we further stated that there was "a real *possibility* that the generic companies would have succeeded against GSK in the patent litigation" (CAT Judgment at [348]) that observation is to be understood accordingly. We did not mean a small possibility, only that we could not say whether the chance was over 50 per cent. We regard that as consistent with the approach of the Decision, finding that the outcome of the patent litigation was "uncertain".

66. It would not be appropriate in this supplementary judgment to rehearse again the evidence on which our conclusion was based, but it included the facts that GUK was prepared to pursue the litigation up to the 'door of the court', settling only days before the patent trial was due to begin, having rejected a number of previous offers; and that Alpharma would have been prepared to launch its product 'at risk' if not effectively enjoined from doing so, and that it did not

consider that it had to settle at all costs. Both GUK and Alpharma are sophisticated generic companies that were no doubt well advised by specialist lawyers and scientific experts; and in our judgment they would not have conducted themselves in this way as against GSK if they thought their position was weak. Moreover, GSK would not have made the Agreements which imposed on itself substantial costs unless it was concerned, as we found, that there was a "real possibility" of the generic companies succeeding.

67. Once generic entry occurred in December 2003, the price of 20 mg paroxetine fell by 34% within three months and by 69% after a year.[7] The fall in price for 30 mg paroxetine (which accounted for about 27% of NHS paroxetine expenditure[8]) was initially more gradual, but after Alpharma entered with a generic product in February 2004. it had fallen by about 50% after a year.[9]

68. We recognise that in the counter-factual, if the patent litigation had proceeded generic entry would not have occurred until after judgment. Judgment in the BASF trial (which was to be heard jointly with the GUK trial if that case had not settled) was given on 12 July 2002. If GUK had fought the case and succeeded, we think it may well have been able to enter pending an appeal or alternatively an appeal would probably have been expedited. And if generic entry occurred with GUK, we cannot see that GSK could have maintained interim relief against Alpharma since the essential ground for an interim injunction was to avoid the sharp fall in price to which generic entry gave rise. Accordingly, we consider that the most probable outcome if GUK had succeeded at trial is that generic entry would have occurred by around January 2003 (if not earlier).

69. It follows that in the absence of the Agreements, if GSK had lost the case against GUK generic entry would have occurred about 11-12 months earlier than it did, with the substantial price effects set out above. Compared with that, the GUK Agreement was concluded in March 2002 and the Alpharma Agreement was concluded in November 2002. The supplies of generic paroxetine pursuant to

[7] CAT Judgment at [54].
[8] CAT Judgment at [13].
[9] Decision, Figure 3.2.

those two Agreements, along with the IVAX Agreement, led to a reduction of no more than 4% in the average price of 20 mg paroxetine. Xellia/ALLC submit that the Decision failed to take this into account in the effects analysis and also that the Decision ignored the benefit from the reduction in PIs: Xellia/ALLC Sub, para 24.2. However, in the first place, although resulting from the Agreements, the small price reduction was not the result of normal competition but of GSK effectively ceding part of the market to the generic companies by supplying them with limited quantities of generic paroxetine for them to sell: see para 55. Secondly, the price reduction was not immediate but occurred over a protracted period due to the change in the mix of supply. And thirdly, the Agreements did not affect the price of 30 mg paroxetine.

70. Although those matters were not referred to again by the CJEU in its discussion of question (6) and restriction by effect, its observations upon them in its earlier discussion of restriction by object are very pertinent. After describing the very matters on which Xellia/ALLC rely, in para 109 of the CJ Judgment (quoted at para 55 above), the CJEU stated, at para 110:

> "Such pro-competitive effects, not only minimal but probably uncertain,[10] cannot be sufficient justification for holding a reasonable doubt, even if those effects are identified by the referring court, that a settlement agreement such as those at issue in the main proceedings revealed sufficient harm to competition, which is in any event exclusively for the referring court to determine."

71. Accordingly, even if we take these factors into account, we find that the real potential for a dramatic fall in price by January 2003 in the counter-factual compared to the earlier but small benefits from the Agreements means that the Agreements were anti-competitive by effect. We would add that if we consider the alternative counter-factual of a less restrictive settlement, the anti-competitive effect of the Agreements was more immediate since in that scenario there would not have been the delay due to a patent trial.

72. We should add that, as a matter of law, we have some doubt that it is even appropriate to have regard to such benefits for the purpose of an effects analysis under Art 101(1) TFEU and sect 2 CA. There is no "weighing up" of different

[10] As to "uncertain", see paras 54-55 above.

effects under Art 101(1), as the CJ Judgment points out at para 104. Those are matters to be considered in the context of exemption under Art 101(3) and sect 9 CA.

73. As to other considerations, Merck relies in particular on risk aversion and asymmetry of information, as it did in the appeal hearing in the CAT and to which it referred in its submissions to the CJEU: Merck Sub, paras 18-19. Such factors are not identified in the CJ Judgment or even mentioned in the AG Opinion. While such factors can be relevant and may be important in analysing contracts, in our view they were insufficient in themselves to justify the very substantial value transfers from GSK to the generic companies when considering anti-competitive object, and we do not see that they can take the matter further in the analysis of anti-competitive effect.

74. Furthermore, the CJEU emphasises the importance of the context and the way in which the particular market functions. In our view, the distinctive features of the pharmaceutical sector highlighted at para 51 of the CJ Judgment, quoted at para 16 above, are very pertinent. We would add that the proper functioning of the patent system (which of its nature involves the exclusion of competitors) is fundamental to the encouragement and reward of successful innovation in this sector, and hence to the consumer interest, but that cannot excuse conduct of the kind condemned in the Decision.

75. As the Advocate General points out, once generic companies are in a position to enter the market (i.e. they can source supplies and have the necessary authorisations), uncertainty as to the patent is a component of the competitive relationship between them and the originator: AG Opinion, para 195. Once it is recognised that each of GUK and Alpharma (and, indeed, IVAX) was a potential competitor to GSK at the time when it entered into the relevant Agreements, the clear effect of that Agreement was completely to remove that *potential* competition for the duration of the Agreement. We do not regard that conclusion as materially different from the CMA's effects case set out in the Decision: see the CAT Judgment at [335].

76. That conclusion does not mean that any settlement of a patent dispute between originator and generic constitutes a restriction of competition by effect. Both Agreements here involved a very substantial transfer of value from GSK to, respectively, GUK and Alpharma, in sums that did not reflect the parties' assessment of patent strength: see the CAT Judgment at [196]-[202]. The Agreements in effect amounted to a sharing of the level of profits GSK would earn so long as independent generic entry was delayed: see in that regard the AG Opinion at paras 197-200.

77. We should only add that in the CAT Judgment, we noted that the Decision on effect was consistent with the Commission's decision in Case AT.39612 – *Perindopril (Servier)*: see CAT Judgment at [339]-[345]. However, we observed that that decision was under appeal to the General Court. The General Court has subsequently given judgment on the appeal: Case T-691/14 *Servier v Commission* EU:T:2018:922. However, since the Court upheld the finding of infringement of Art 101[11] on the basis of a restriction by object, it held that it was unnecessary to address the question of whether there was also a restriction by effect: judgment at paras 566-570, 743, 909 and 1247. The General Court judgment accordingly does not take the Commission's decision on this point any further and we remain under an obligation to take that decision into account, now pursuant to s. 60A(3) CA.

Conclusion

78. Accordingly, we dismiss the appeals against the Decision in respect of the finding that the GUK and Alpharma Agreements were anti-competitive by effect.

[11] Save in regard to the different forms of agreement entered into by Servier with Krka, which were not analogous to the Agreements here and where the Court found that the Commission had not established that Krka would have entered the market in the absence of those agreements: paras 943-1234.

E. WHAT IS THE RELEVANT PRODUCT MARKET FOR THE PURPOSE OF ASSESSMENT OF DOMINANCE?

79. The Decision found that GSK had abused its dominant position by entering into the Agreements and also the IVAX Agreement. By its appeal, GSK challenged both the finding of dominance and the finding of abuse. Its challenge to dominance depends on the definition of the relevant product market: CAT Judgment, paras 379-380. This was the subject of question (7) in the reference to the CJEU.

80. To place the CJ Judgment on this question in context, it is necessary to summarise how the issue arose.

81. In the Decision, the CMA rejected GSK's argument that the relevant market comprised all anti-depressants known as SSRIs[12] and held that it was confined to paroxetine. The Decision reached that conclusion after conducting a qualitative analysis, which it found was of only theoretical value and inconclusive, and a quantitative analysis which found that other SSRIs constrained the price of paroxetine to a much lesser degree than generic paroxetine once that entered the market.

82. In our judgment, we held that the qualitative evidence was not inconclusive but showed that there were no significant therapeutic distinctions between paroxetine and other SSRIs; and that the fact that patented paroxetine faced little competitive constraint from other drugs in matters of price is not decisive when demand for such prescription medicines was not price-sensitive: CAT Judgment at [399]-[401].

83. However, we emphasised that market definition is only a means to the end of assessing dominance and was essentially a question of determining which other products act as a material competitive constraint on the allegedly dominant firm. We held that market definition should not be seen as static but could change over time. The CAT Judgment states, at [402]:

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[12] Selective serotonin re-uptake inhibitors.

> "There was a large degree of therapeutic equivalence between paroxetine and other SSRIs. They provided some competitive constraint in that they stimulated GSK's promotional efforts to persuade doctors to prescribe paroxetine. Thus we accept that before generic companies became potential entrants paroxetine probably did not constitute a separate market. But in our view, that degree of competition between alternative SSRIs pales into insignificance compared to the effect of generic paroxetine. It is the competitive effect of generic entry which was the incentive for GSK to conclude the Agreements here at issue. Moreover, we think it is not illogical to find that as a pharmaceutical product approaches the stage when generic entry becomes a realistic possibility, the generic product is then taken into account in determination of competitive constraints and thus market definition, although years beforehand when there was no realistic prospect of a challenge to the patent on the active pharmaceutical ingredient, generic companies would not be regarded as relevant to market definition. Dr Reilly explained that it was from the time that data exclusivity under the MA expired … that generic entry is regarded as a realistic threat, and that the situation with paroxetine was unusual because for historical reasons the data exclusivity ended much earlier before patent expiry than is normally the case."

84. In addition, we were attracted by the opinion of the expert economist called by the CMA, Professor Shapiro, that the definition of the relevant market may depend on the conduct under scrutiny: the *relevant* market may therefore be different when considering exclusionary conduct from a case concerning another form of abuse, such as a product tie: CAT Judgment at [395], [402]-[404].

85. Further, we considered that there was an independent reason on the evidence for finding that paroxetine was the relevant market. This was the competitive constraint imposed by parallel imports ("PIs"). That was not a reason relied on, or indeed referred to, in the Decision. See the CAT Judgment at [407].

86. Neither the Advocate General nor the CJEU gives any support to the concept of the relevant market being assessed according to the conduct under scrutiny. However, the CJ Judgment, following the AG Opinion, expressly finds that the market definition can change once a pharmaceutical drug reaches the stage where generic companies are preparing to enter. The Advocate General states:

> "222. Such an examination of the competitive constraints faced by a certain undertaking, based on the conditions of competition and the structure of supply and demand on a certain market, is naturally dynamic in character. It is therefore quite conceivable that the emergence of a new supply of products alters the structure of the relevant market in such a way as to exclude other products which previously formed part of it. It follows that, in the present case, it cannot be ruled out that the relevant market on which paroxetine evolved

> was, as the CAT appears to consider, composed of all SSRIs at the beginning of the life-cycle of that active substance, whereas that market altered in such a way as to comprise only paroxetine when the threat of market entry by the generic versions of that molecule emerged.
>
> 223. It should be noted, however, that in the context of the preliminary ruling procedure established by Article 267 TFEU, any assessment of the facts of the case falls within the competence of the referring court…"

87. The CJ Judgment clearly accepts this approach:

> "130 In that context, and as the Advocate General stated, in essence, in point 222 of her Opinion, the interchangeability or substitutability of products are naturally dynamic, in that a new supply of products may alter the conception of the products considered to be interchangeable with a product already present on the market or as substitutable for that product and, in that way, justify a new definition of the parameters of the relevant market.
>
> 131 As regards, in particular, the definition of the product market to which, for the possible application of Article 102 TFEU, an originator medicine belongs such as, in the main proceedings, the paroxetine marketed as 'Seroxat', which can be therapeutically substituted with other SSRIs, it is clear from the point made in the preceding paragraph of the present judgment that a supply of generic medicines containing the same active ingredient, in this case paroxetine, could lead to a situation where the originator medicine is considered, in the professional circles concerned, to be interchangeable only with those generic medicines and, consequently, to belong to a specific market, limited exclusively to medicines which contain that active ingredient."

88. There remains the question of whether generic versions of the pharmaceutical product can be regarded as being in the same market when the originator relies on patent protection to prevent their entry. The CJEU makes clear that they can only be in the same market once the generic companies are in a position to enter "within a short period on the market concerned with sufficient strength to constitute a serious counterbalance to the manufacturer of the originator medicine already on the market" (para 133). The CJ Judgment continues:

> "134 That is accordingly true where, on the expiry of the patent relating to the active ingredient concerned, or of the data exclusivity period of that active ingredient, those manufacturers of generic medicines are in a position to enter the market immediately or within a short period, particularly where those parties have formed a prior effective strategy for market entry, have taken the steps necessary to achieve it, such as, for example, the lodging of an MA application or the obtaining of such an MA, or have concluded supply contracts with third-party distributors.
>
> 135 In that regard, as stated by the Advocate General in point 239 of her Opinion, evidence of the perception, by the manufacturer of originator medicines, of the immediacy of the threat of market entry by the manufacturers

> of generic medicines might also be taken into account in order to assess the significance of the competitive constraints imposed by the latter.
>
> 136 The fact that the manufacturer of originator medicines relies on an intellectual property right over the process of manufacturing the active ingredient concerned as capable of possibly impeding the market entry of generic versions of the originator medicine containing that active ingredient cannot be sufficient ground for any other finding."

89. Applying this reasoning, and given our findings as to the ability of the generic companies to enter the market absent any impediment from GSK's assertion of patent rights, we think that it is clear on the facts that by the time when GSK concluded its successive agreements with IVAX, GUK and Alpharma, the generic products should be regarded as exercising a competitive constraint so as to constitute part of the relevant market.

90. On that basis, and the additional ground of competition from the PIs referred to above, we find that at the material time the relevant market comprised paroxetine. GSK's submissions against that conclusion are based on the errors that we found in the CMA's reasoning in the Decision. However, the Tribunal is entitled to uphold the Decision on other grounds. Indeed, the Tribunal on an appeal under sects. 46 CA is entitled to make any decision which the CMA could itself have made: CA Sch 8, para 3(2)(e). Given the express terms of the statute, we reject GSK's submission that it would be "entirely inappropriate" for the Tribunal to uphold the finding of market definition on a different basis from that set out in the Decision: GSK Sub, para 25.

Conclusion

91. Accordingly, we dismiss Ground 1 of GSK's appeal challenging the finding of dominance in the Decision on the basis of the CMA's definition of the relevant product market.

F. DID GSK ABUSE ITS DOMINANT POSITION?

92. The Decision on abuse relates not only to the GUK and Alpharma Agreements but also to the earlier IVAX Agreement.

93. In the CAT Judgment, we found the following facts, on the balance of probabilities:

(1) IVAX would have been able to source paroxetine independently of GSK and if it had not concluded the IVAX Agreement it would have sought to enter the market independently: [418]-[419];

(2) GSK regarded IVAX as a potential competitor at the time: [418];

(3) If IVAX had sought to enter the market GSK would have commenced patent proceedings against it, and it is uncertain which side would have succeeded in such proceedings: [419];

(4) GSK was pursuing a strategy of seeking to preclude the risk of generic entry by concluding agreements whereby the generic company was induced to delay its effort to enter the market independently in consideration for a significant value transfer that included limited generic supply: [426].

(5) The IVAX Agreement, by introducing a significant quantity of 20 mg generic paroxetine onto the market, led to the reclassification of paroxetine under the NHS Drug Tariff from June 2002, which led to a significant saving for the NHS by reason of the consequent lower reimbursement price: [275], [278] and [420].

(6) This reduction in the price paid by the NHS was no part of the intention of the parties when entering into any of the Agreements at the time: [279].

94. In the light of those findings, the issue of abuse was the subject of questions (8)-(10) referred to the CJEU.

The CJ Judgment

95. The CJEU considered this issue in terms of a single abuse based on the finding set out at para 93(4) above (as opposed to each individual agreement constituting a separate abuse): CJ Judgment at paras 142-143.

96. The CJEU noted that the conclusion of a settlement agreement between a patent holder that is in a dominant position and parties allegedly infringing that patent in order to end patent litigation between them cannot of itself constitute an abuse: para 150. But the CJ Judgment continues (omitting citations):

> "151 However, such conduct cannot be accepted when its purpose is precisely to strengthen the dominant position of the party engaging in it and to abuse that position as when such conduct is intended to deprive parties demonstrated to be potential competitors of effective access to a market, such as that of a medicine containing an active ingredient that is in the public domain.
>
> 152 Accordingly, when the intention of a manufacturer of originator medicines holding a dominant position is to protect its own commercial interests, in particular by defending its patents, and to guard itself against the competition of generic medicines, that alone does not justify resorting to practices that fall outside the scope of competition on the merits.
>
> […]
>
> 155 In this case, the information contained in the documents available to the Court indicate that the CMA and the referring court considered that the set of settlement agreements concluded on the initiative of GSK were part of an overall strategy on the part of that manufacturer of originator medicines and had, if not as their object, at least the effect of delaying the market entry of generic medicines containing the active ingredient 'paroxetine' that had earlier entered the public domain and, therefore, of preventing a significant fall in the prices of the originator medicines containing that active ingredient and produced by GSK; the direct consequence of that entry would have been an appreciable reduction in GSK's market share and an equally appreciable reduction in the sale price of its originator medicine.
>
> 156 However, such a contract-oriented strategy, the actual nature of which it is for the referring court to determine having regard to the evidence available to it, constitutes, in principle, a practice that impedes, while adversely affecting at least the national health systems if not the final consumer, the growth of competition in the market of a medicine containing an active ingredient that is in the public domain.
>
> 157 The anticompetitive effects of such a contract-oriented strategy are liable to exceed the anticompetitive effects inherent in the conclusion of each of the agreements that are part of it. That strategy has a significant foreclosure effect on the market of the originator medicine containing the active ingredient at issue, depriving the consumer of the benefits of entry into that market of

> potential competitors manufacturing their own medicine and, therefore, reserving that market directly or indirectly to the manufacturer of the originator medicine concerned.
>
> 158 In that regard, the fact, alluded to in the context of Question 9, that one of the settlement agreements at issue, namely the GSK/IVAX agreement, was entered into not to settle existing court proceedings but to avoid the bringing of such proceedings is immaterial.
>
> 159 Likewise, the fact that one of the settlement agreements concluded by that manufacturer of originator medicines, in this case the GSK/IVAX agreement, … might have led to substantial savings for the national health system cannot in itself call into question the finding that such a strategy existed and that it constituted an abuse."

97. The CJEU added that a finding that the conclusion of the settlement agreements was part of an overall strategy by GSK to maintain its monopoly position in the UK paroxetine market may further be taken into account in order to determine the question of abuse: paras 163-164.

98. The CJEU then observed that it is open to the dominant company to show justification for the conduct impugned,

> "in particular by establishing that the exclusionary effect produced by its conduct may be counterbalanced, or outweighed, by advantages in terms of efficiency that also benefit consumers…." (para 165).

99. The CJ Judgment proceeds to explain the approach to be adopted to such potential justification and to comment on its application in the present case:

> "166 To that effect, it is for the dominant undertaking to show that the efficiency gains likely to result from the conduct under consideration offset any likely negative effects on competition and the interests of consumers in the affected markets; that those gains have been, or are likely to be, brought about as a result of that conduct; that such conduct is necessary for the achievement of those efficiency gains, and that it does not eliminate effective competition, by removing all or most existing sources of actual or potential competition (judgment of 27 March 2012, *Post Danmark*, C-209/10, EU:C:2012:172, paragraph 42), and consequently that undertaking has to do more than put forward vague, general and theoretical arguments on that point or rely exclusively on its own commercial interests.
>
> 167 It follows that the assessment of whether a practice that may be subject to the prohibition laid down in Article 102 TFEU is justified requires, inter alia, a weighing of the favourable and unfavourable effects on competition of the practice concerned (judgment of 6 September 2017, *Intel* v *Commission*, C-413/14 P, EU:C:2017:632, paragraph 140), which requires objective analysis of its effects on the market.

> 168 Accordingly, the taking into consideration of, inter alia, the efficiency gains of the practices concerned cannot depend on the objectives that may have been pursued by the party engaged in those practices and, therefore, on whether those practices result from deliberate intention or, on the contrary, are only fortuitous or accidental.
>
> […]
>
> 170 Consequently, the fact that the financial implications of the GSK/IVAX agreement that are favourable to the national health system, referred to in Question 10(b), may have been accidental cannot have the result that, for that reason alone, such financial implications are excluded from the weighing of favourable and unfavourable effects on competition of the practice concerned, and those financial implications must therefore be duly taken into account in order to assess whether they do constitute efficiency gains that may arise from the conduct under examination and, if so, whether they offset the adverse effects that that conduct is capable of having on competition and the interests of consumers in the market affected.
>
> 171 In that regard, it must be stated that that weighing of effects should be carried out taking due account of the specific characteristics of the practice concerned and more particularly, with respect to a unilateral practice such as that at issue in the main proceedings, of the fact mentioned by the referring court in Question 10(b), namely the fact that the demonstrated favourable effects resulting from the GSK/IVAX agreement are significantly less than those which would have arisen upon the independent market entry of a generic version of Seroxat following a successful outcome for IVAX in the patent proceedings."

100. The section of the CJ Judgment answering the questions on abuse concludes at para 172, which is effectively repeated in para 5 of the operative part of the ruling:

> "…the answer to Questions 8 to 10, taken together, is that Article 102 TFEU must be interpreted as meaning that the strategy of a dominant undertaking, the holder of a process patent for the production of an active ingredient that is in the public domain, which leads it to conclude, either as a precautionary measure, or following the bringing of court proceedings challenging the validity of that patent, a set of settlement agreements which have, at the least, the effect of keeping temporarily outside the market potential competitors who manufacture generic medicines using that active ingredient, constitutes an abuse of a dominant position within the meaning of Article 102 TFEU, provided that that strategy has the capacity to restrict competition and, in particular, to have exclusionary effects, going beyond the specific anticompetitive effects of each of the settlement agreements that are part of that strategy, which it is for the referring court to determine.

Submissions and Discussion

101. GSK relies on the formulation in para 172 quoted above to submit that this test is not fulfilled since although the Decision, upheld in this respect by the CAT

Judgment, found that GSK had pursued an exclusionary strategy, it had not been shown that this had any exclusionary effect "going beyond the specific anticompetitive effects of each of the settlement agreements that are part of that strategy." GSK also submits that for this purpose "the competitive benefits brought about by that strategy" should be brought into account, including the effect of the IVAX Agreement on the reimbursement price of paroxetine under the NHS Drug Tariff: GSK Sub, paras 28-31.

102. However, after referring to the effect of each Agreement in preserving GSK's dominant position, the Decision found, at para 8.56:

> "The anti-competitive effects of the Agreements were reinforced because together they helped to make sure that each threat of potential independent generic entry was deferred, and that there was no material increase in the actual competitive constraints that GSK faced."

103. We affirmed that approach in the CAT Judgment, stating at para 426:

> "… we found that GSK was pursuing a conscious strategy of seeking to preclude the risk of generic entry by concluding agreements of this nature whereby the generic challenger was induced to delay its effort to enter the market independently in consideration for a significant value transfer that included limited generic supply. For the purpose of the Chapter II prohibition, which is directed at the conduct of the dominant undertaking, we think it is relevant to focus on the course of conduct adopted by GSK and therefore to look at the three Agreements as a whole."

104. Indeed, we consider it is almost inevitable that a conscious strategy of seeking to prevent unrestricted generic products coming onto the market, put into effect by making a series of agreements with each of the first three generic companies to threaten entry, "has the capacity" to have an overall anti-competitive effect beyond that of each agreement considered in isolation, as the CJEU indicates at para 157 of the CJ Judgment. We do not regard the fact that GSK subsequently did not settle the patent claim against Apotex, which went to trial in June 2003, as undermining this assessment of the effect of GSK's conduct: such a strategy does not imply that GSK is bound to settle with every generic challenger going forward. We therefore find that the facts satisfy the test for abuse in the CJ Judgment.

105. As for any "competitive benefits", the CJ Judgment is clear that such matters, including specifically the effect of the IVAX Agreement on the NHS reimbursement price, do not affect the prima facie finding of abuse but fall to be assessed in the context of objective justification. That depends on the dominant company showing that the Agreements led to efficiency gains, meeting the strict conditions for objective justification set out in *Post Danmark.* It is manifest that none of the Agreements meets those conditions: e.g. persuading IVAX not to pursue its threatened patent challenge and restricting GUK and Alpharma from continuing their patent challenges were obviously not necessary to achieve the reclassification under the Drug Tariff. Indeed, in its Notice of Appeal GSK stated (at para 9.35):

> "GSK does not suggest that its entry into the Agreements, though anticompetitive, was justified on the basis that they created efficiency gains. Its case is that the Agreements were not anticompetitive at all…."

Conclusion

106. Accordingly, we dismiss ground 6 of GSK's appeal and uphold the finding of abuse.

G. PENALTIES

107. The CMA imposed financial penalties on the Appellants as follows:

GSK	£37,606,275
GUK-Merck: total penalty	£5,841,286 for which:
- Merck is liable for	£ 5,841,286
- GUK is jointly and severally liable for	£ 2,732,765
Alpharma: total penalty	£ 1,542,860 for which
- Actavis, Xellia and ALLC are jointly and severally liable	

108. All the Appellants challenge the imposition of these penalties, arguing that no penalty should have been imposed at all or alternatively that the level of penalty was too high. This was ground 7 of GSK's appeal; grounds 6 and 7 of GUK's appeal; ground 4 of Merck's appeal; ground 5 of Actavis' appeal; and ground 5 of Xellia/ALLC's appeal.

109. On an appeal, the Tribunal may impose or revoke or vary the amount of a penalty: para 3(2) of Sch 8 CA.

110. The statutory basis for the imposition of penalties for breaches of the Chapter I and Chapter II prohibitions and, at the relevant time, Art 101 TFEU is s. 36 CA, of which the material parts are as follows:

> "(1) On making a decision that conduct has infringed the Chapter I prohibition or that it has infringed the prohibition in Article 101, the CMA may require the undertaking concerned to pay the CMA a penalty in respect of the infringement.
>
> (2) On making a decision that conduct has infringed the Chapter II prohibition … , the CMA may require the undertaking concerned to pay the CMA a penalty in respect of the infringement.
>
> (3) The CMA may impose a penalty on an undertaking under subsection (1) or (2) only if the CMA is satisfied that the infringement has been committed intentionally or negligently by the undertaking.
>
> …
>
> (7A) in fixing a penalty under this section the CMA must have regard to –
>
> (a) the seriousness of the infringement concerned, and
>
> (b) the desirability of deterring both the undertaking on whom the penalty is imposed and others from-
>
> (i) engaging in conduct which infringes the Chapter 1 prohibition or the prohibition in Article [101(1)], or
>
> (ii) engaging in conduct which infringes the Chapter 2 prohibition or the prohibition in Article [102].
>
> (8) No penalty fixed by the CMA under this section may exceed 10% of the turnover of the undertaking (determined in accordance with such provisions as may be specified in an order made by the Secretary of State)."

111. The CMA is required to publish guidance as to the appropriate amount of the penalty, and when setting the amount of a penalty the CMA and the Tribunal

must have regard to that guidance: s. 38(1) and (8). At the material time, the guidance in force was the OFT's *Guidance as to the appropriate amount of a penalty* (OFT 423, September 2012), adopted by the CMA Board (the "Penalty Guidance").

112. The Penalty Guidance sets out a six-step approach to the calculation of the amount of a penalty:

(1) Step 1: the starting point. This is calculated having regard to the seriousness of the infringement applied as a rate of up to 30 per cent to the turnover of the undertaking in the relevant market;

(2) Step 2: adjustment for duration;

(3) Step 3: adjustment for aggravating or mitigating factors;

(4) Step 4: adjustment for specific deterrence and proportionality;

(5) Step 5: adjustment if the maximum penalty[13] of 10 per cent of the worldwide turnover or (for an infringement which ended prior to 1 May 2004) the UK turnover of the undertaking is exceeded;

(6) Step 6: adjustment for leniency and settlement discounts.

Was the CMA entitled to impose a penalty?

113. The Appellants allege that the infringements were not committed intentionally or negligently, such that the condition for imposition of a penalty in s. 36(3) CA was not satisfied.[14]

[13] Under s. 36(8) CA and the Competition Act 1998 (Determination of Turnover for Penalties Order 2000 (as amended).

[14] Actavis did not raise this ground in its Notice of Appeal but has done so following the CJ Judgment: Actavis Sub, paras 34-39. We think it would be wrong to preclude it from advancing this ground which causes no prejudice to the CMA (and if necessary we would permit Actavis to amend its Notice of Appeal).

114. The Tribunal considered the meaning of "intentionally" and "negligently" in its judgment on the first appeal against a decision finding infringement of the CA: *Napp Pharmaceutical Holdings Ltd v DGFT ("Napp")* [2002] CAT 1. The Tribunal stated (omitting citations of EU authorities):

> "456…. an infringement is committed intentionally for the purpose of section 36(3) of the Act if the undertaking must have been aware, or could not have been unaware, that its conduct had the object or would have the effect of restricting competition…. While in some cases the undertaking's intention will be confirmed by internal documents, in our judgment, and in the absence of any evidence to the contrary, the fact that certain consequences are plainly foreseeable is an element from which the requisite intention may be inferred.
>
> 457 … an infringement is committed negligently for the purposes of section 36(3) if the undertaking ought to have known that its conduct would result in a restriction or distortion of competition…."

115. The same condition applies under EU competition law for the imposition of penalties by the Commission for breach of the equivalent prohibitions. In Case C-280/08 P *Deutsche Telekom v Commission* EU:C:2010:603, the CJEU stated, at para 124:

> "the question whether the infringements were committed intentionally or negligently… is satisfied where the undertaking concerned cannot be unaware of the anti-competitive nature of its conduct, whether or not it is aware that it is infringing the competition rules of the Treaty."

116. In Case C-681/11 *Bundeswettbewerbsbehörde v Schenker & Co* EU:C:2013:204, the CJEU stated, at para 38:

> "… 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 be unaware of the anti-competitive nature of that conduct."

117. These are the principles applicable for the purpose of s. 36(3) CA, as recently confirmed by the Court of Appeal: *Ping Europe Ltd v CMA* [2020] EWCA Civ 13 at [117].

118. Accordingly, this is a threshold question determining the jurisdiction of the CMA to impose a penalty. It does not go to the separate issue of the level of the penalty or, indeed, whether for particular reasons no penalty should here have been imposed. In *Napp*, the Tribunal held, at [455], that in determining whether

the statutory threshold is met, it is not necessary to specify or determine whether the infringement was committed intentionally or negligently so long as it was either one or the other.

119. The Appellants emphasise that the Agreements were made in 2001-2002, at a time when it had not been suggested that patent settlement agreements of that kind contravened competition law. They stress, as they did on the issues of infringement, that the Agreements in fact allowed an element of entry by the generic companies onto the market. For this and other reasons, they argue that the findings in the Decision were wholly novel and could not have been foreseen.

120. We address this argument separately as regards the Chapter I prohibition (and Art 101) and as regards the Chapter II prohibition.

Chapter I prohibition (and Art 101 TFEU)

121. It should be stressed that the question is whether the relevant undertakings knew or should have known at the time not that the Agreements infringed competition law but that they were anti-competitive in nature. In that respect, we note that we found that both GUK and Alpharma intended to enter the market and challenge GSK's patents, and were ready for that purpose to engage in patent litigation with GSK. It was clear to everyone that if such entry had been achieved, the resulting generic competition would have caused a rapid and very substantial fall in the price of both 20 mg and 30 mg paroxetine. The patent litigation was averted and the potential for independent entry by the generic companies was precluded by the Agreements, which involved the transfer of very substantial values by GSK to, respectively, GUK and Alpharma.

122. Moreover, we found that although the Agreements described significant sums to be paid by GSK as "marketing allowances" (£1.65 million p.a. in the GUK Agreement; £1.2 million for the year under the first Alpharma Agreement), the parties were aware that those sums bore no relation to any expected marketing expenditure. We held that the same applied to the so-called "promotional allowance" (£3.2 million) under the IVAX Agreement. See the CAT Judgment

at [177]-[180]. The fact that the parties gave misleading descriptions to substantial payments that were in reality part of the consideration for the generic companies delaying their patent challenges, in our view, supports the conclusion that they either were, or at least ought to have been, aware, that the true nature of their agreements had an anti-competitive character.

123. As we noted in the CAT Judgment, the fact that under the Agreements GSK supplied the generic companies with a limited quantity of 20 mg paroxetine for them to sell on the UK market in generic form did not introduce competition between the generic companies and GSK, and resulted in only a modest fall in the price of that product while having no effect on the price of 30 mg paroxetine. This arrangement therefore enabled the generic companies to sell their permitted supplies at significantly higher prices than would have been realised if they had been able to enter independently with their own generic product. Accordingly, we do not consider that this casts doubt on the conclusion that the parties ought to have been aware of the anti-competitive nature of the Agreements, on the basis that they excluded potential generic entrants from the market by making very substantial transfers of value. This is irrespective of any precedents in competition law.

124. The fact that several issues of law justified a reference does not in itself mean that the infringement was not intentional or negligent: if it were otherwise, whenever a reference is made by a national court concerning an infringement decision, no penalty could be imposed. It was the question of anti-competitive effect that we found particularly uncertain, but an anti-competitive object is of course a sufficient basis to find that an agreement potentially restricts competition. This was clearly an important case, in which powerful arguments were advanced. Moreover, in the present case a particular reason for the reference was that the Tribunal held that it was otherwise bound by the judgments of the General Court in the *Lundbeck* cases, which were themselves on appeal to the CJEU (and which several of the Appellants submitted were wrong): CAT Judgment at [319] and [326].

125. Nor does the fact that at the time there was no legal precedent holding that an agreement of this nature infringed competition law preclude a finding that the

infringement was committed intentionally or negligently: cp Case C-457/10 P *AstraZeneca* EU:C:2012:770 at para 164. As stated above, the question is not whether the Appellant should have known that the agreements were against the law but that they had an anticompetitive nature.

126. We accordingly find that the Appellants cannot have been unaware that the Agreements had the potential appreciably to restrict competition. That conclusion is reinforced by the judgments of the General Court on precisely this issue in the *Lundbeck* cases: CAT Judgment at [85]. The patent settlement agreements involved in *Lundbeck* were similarly made in 2002. In Case T-472/13 *Lundbeck* EU:T:2016:449, dismissing similar arguments regarding the penalty to those addressed by the present Appellants, the General Court stated, at para 783:

> "Furthermore, just as in the case that gave rise to the judgment in *AstraZeneca*, cited in paragraph 755 above (EU:T:2010:266), the applicants' conduct in the present case was clearly not part of normal competition, since they aimed to exclude potential competitors from the market by means of significant reverse payments. The fact that some patent settlement agreements, moreover, may be legitimate and not infringe the provisions of the Treaty on free competition does not alter the fact that, in the present case, the agreements at issue concluded by the applicants were anticompetitive, for the reasons set out by the Commission in the contested decision …."

127. We note in addition that the judgment records the finding by the Commission that certain generic companies refused to enter into agreements with Lundbeck similar to those at issue in the case precisely because they realised that such agreements were anti-competitive and might infringe competition law: *Lundbeck*, para 776.

128. The General Court also addressed the separate but related argument that the imposition of a penalty infringed the principle of legal certainty because the law was unclear at the time of the agreements. The same argument is in effect advanced by Merck and Xellia/ALLC: Merck Sub, paras 33 et seq; Xellia/ALLC Sub, para 29. The Court recalled that already in 1974 the Court of Justice had held that the exercise of an intellectual property right could fall under the prohibitions in Art 101(1): Case 15/74 *Centrafarm and de Peijper* EU:C:1974:114, paras 39 and 40; and that in 1988 it had held that an agreement is not exempt from competition law merely because it is made in settlement of

a patent dispute: Case 65/86 *Bayer and Maschinenfabrik Hennecke* EU:C:1988:448, para 15. The General Court stated:

> "764 In the present case, contrary to what the applicants claim, it was not unforeseeable that agreements by which the originator company was able to remove potential competitors from the market for a specified period, by means of significant reverse payments, might be contrary to Article 101(1) TFEU, whether or not they went beyond the scope of that company's patents (see paragraphs 487 to 491).
>
> 765 As the Commission stated correctly in recitals 1312 and 1313 of the contested decision, a literal reading of Article 101(1) TFEU made it clear that agreements between competitors for the exclusion of some of them from the market were illegal. Market-sharing or exclusion agreements are among the most serious restrictions of competition expressly referred to in Article 101(1) TFEU (paragraph 338 above).
>
> 766 The fact that, in the present case, the agreements at issue were concluded in the form of settlement agreements concerning intellectual property rights cannot allow the applicants to infer that their unlawfulness under competition law was completely novel or unforeseeable.

129. The judgments of the General Court in *Lundbeck* are binding on the Tribunal as regards application of the equivalent provisions enabling the imposition of a penalty under the CA, pursuant to s. 60A(2). On 25 March 2021, the CJEU finally issued its judgments in *Lundbeck* on the appeals from the General Court: Cases C-586/16P *Sun Pharmaceutical Industries and Ranbaxy (UK) v Commission* EU:C:2021:241, C-588/16P *Generics (UK) v Commission* EU:C:2021:242, C-591/16P *Lundbeck v Commission* EU:C:2021:243, C-601/16P *Arrow Group and Arrow Generics v Commission* EU:C:2021:244, C-611/16 P *Xellia Pharmaceuticals and Alpharma v Commission* EU:C:2021:245, and C-614/16 P *Merck v Commission* EU:C:2021:246. Since those judgments came after 31 December 2020, they are not binding on the Tribunal but could provide a ground for departing from the decisions of the General Court: s. 60A(7)(e) CA. There is no such ground here, since the CJEU upheld the General Court's reasoning and dismissed all the appeals.

130. However, we emphasise that the fact that the jurisdiction to impose a penalty is therefore established does not mean that it is inappropriate to mitigate the penalty because of the novelty of the infringement or on other grounds: see paras 179-186 below.

Chapter II prohibition

131. Aside from the question of abuse, on which GSK relies on the same arguments as in respect of the Chapter I prohibition, GSK contends that it could not reasonably have been aware in 2001-2002 that it held a dominant position. The holding of a position of such substantial market power is of course an essential element of infringement of the Chapter II prohibition. The essence of the anti-competitive abuse is that the conduct reinforces or enhances a dominant position by means other than competition on the merits. If an undertaking does not hold a dominant position, the impugned activity does not have the same anti-competitive effect.

132. The CMA's finding that GSK should have been aware that it may well hold a dominant position is not contained in section 11 of the Decision but is set out in Annex K at para 8(a):

> "the fact that it expected significant falls in its prices and profits following generic entry was indicative of it holding substantial market power at the time the Agreements were entered into"

133. We do not consider that this alone could indicate a holding of significant market power. A significant fall in price following generic entry is a feature of most patented medicines, and if that was sufficient to show a likelihood of dominance then almost every patent-holder would be dominant. That is not the case, as shown by the recent judgment of the General Court in Case T-691/14 *Servier v Commission*, EU:T:2018:922. The critical question is whether the relevant market is confined to the patented product and to potential entrants offering non-patented versions of the same molecule.

134. In section 4 of the Decision, the CMA found that GSK was dominant relying only on a quantitative analysis for market definition, essentially on the same basis of the fall in price after generic entry. As noted at para 90 above, we rejected that approach but found that the definition could be supported on several other grounds. The approach of the Tribunal and the ruling on this issue by the CJEU are summarised at paras 82 to 89 above.

135. In the light of that, GSK submits that the approach adopted by the CJEU is wholly novel and could not have been foreseen in 2001-2002. It points out that the Commission's *Notice on Market Definition* (1997) OJ C 372/5 states that "*potential competition is not taken into account when defining markets*" (para 24). If that were all, we would see force in GSK's argument that it cannot be said that it should have been aware at the time of the Agreements that it had substantial market power as regards paroxetine. However, that is not all. We found as a distinct ground that the competitive constraint from PIs and GSK's response to that threat demonstrated that paroxetine was a distinct market at the time: CAT Judgment at [407]. This was not the subject of a question to the CJEU. GSK was clearly well aware of that constraint: indeed, it was the equalisation deals which GSK offered specifically on the 20 mg product that demonstrated the constraint (since there were no PIs of 30 mg paroxetine). We therefore find that GSK should have known that paroxetine was a distinct product market, in which it therefore had substantial market power.

Limitation

136. GSK and Xellia/ALLC contend that principles of legal certainty and administrative fairness are infringed on the distinct ground of limitation, pointing to Art 25 of Reg 1/2003 which precludes the Commission from imposing a penalty if it does not open an investigation within five years from the end of the infringement. Here, the Agreements apparently came to the attention of the Commission in the course of its inquiry into the pharmaceutical sector, launched in 2008 and concluded in July 2009, and the Commission then passed copies of the Agreements to the OFT in July 2010. By that stage, the limitation period had expired for the Commission to impose fines if it had then opened an investigation.

137. However, it is common ground that there is no limitation period for an investigation or the imposition of a penalty under the CA. There is no basis for, in effect, importing a limitation period into the UK regime when the domestic legislation has chosen to take a different path in this respect from the EU legislation. As the Tribunal has previously observed, Parliament did not intend that the UK competition authority should be subject to such a specific constraint:

Quarmby Construction Co Ltd v OFT [2011] CAT 11 at [56]. As for administrative fairness, in our view that does not go to jurisdiction but applies more appropriately to the question whether a penalty should be imposed in this case. But in any event, there is no basis to suggest that the passing of the papers by the Commission to the OFT was a deliberate strategy to get round the EU limitation period. The Agreements concerned only the UK and where an investigation concerned only one Member State the Commission frequently considers that it is more appropriately carried out by that State's competition authority.

Should the CMA have imposed a penalty?

138. GSK and Merck in particular argue that even if the jurisdictional threshold was crossed, this was a case where no penalty, or only a nominal fine, should have been imposed because of the novelty and complexity of the case. They point to some EU decisions and judgments where that approach was adopted.

139. Inevitably, this argument overlaps somewhat with the jurisdictional argument discussed above, but it is conceptually distinct. Moreover, we think that there is a marked difference between a decision to impose no penalty at all as opposed to a decision reducing the penalty on account of special circumstances.

140. In the first place, it should be emphasised that each case is different and an assessment of novelty excusing a fine is very dependent on the particular facts and circumstances of the case. As regards the EU decisions and judgments on which GSK and Merck seek to rely:

    (1) Case T-86/95 *Compagnie Générale Maritime*, EU:T:2002:50: there the Court of First Instance found that although the parties were aware of the anti-competitive character of their liner conference agreement, it involved long-standing and public price-fixing which dated back to a period before the Commission itself had defined its position on the application of the competition rules to maritime transport. The Commission's own conduct had led the shipping companies to believe that their agreement was not unlawful. And by a decision adopted

shortly beforehand, the Commission had imposed no penalty on the parties to another liner conference. See the judgment at paras 481-487.

(2) Case Comp/D1/37860 *Visa Europe* (2007): that was not a case where the Commission imposed a nominal penalty. Visa had notified the rule in question and was accordingly immune from penalty for the period until Reg 1/2003 came into force on 1 May 2004. The Commission imposed a substantial penalty of €10.2 million on the parties for the period after the issue of the Statement of Objections on 2 August 2004: see recitals (341), (349) and art 2.

(3) Case Comp/38.096 *Clearstream (Clearing and Settlement)* (2004): there the Commission decided not to impose a fine since there was not only no EU decisional practice or case law relating to the complex area of clearing and settlement services, but institutions such as the European Bank had actively debated the proper role of central securities deposits ("CSDs") and international CSDs and their relationship with custodian banks, which lay at the heart of the abusive conduct: see recital (344).

(4) Case IV.31.906 *Italian flat glass* (1988): the three Italian glass manufacturers were found to have infringed simultaneously both Art 85(1)[now Art 101(1)] and Art 86 [now Art 102] for the same period. No fine was imposed for the latter violation as it was the first time that the Commission used the concept of collective dominance: recital (84(a)). However, very substantial fines were imposed for the same conduct when characterised as a breach of Art 85(1): art 4.

(5) Case IV/31.128 *Fatty acids* (1986): the Commission found that the infringement was intentional or at least negligent but imposed a fine of only 50,000 ECU on the three undertakings because it was the first case in which it imposed a fine for a pure exchange of information agreement: recitals (55), (58)-(59).

(6) Case Comp/C-1/36.195 *Deutsche Post AG* (2001): the Commission found that Deutsche Post ("DP") must have been aware that its conduct

in surcharging a large proportion of mail from other Member States had adverse effects on competition. Although jurisdiction to fine was thus established, the Commission imposed only a nominal penalty because (a) DP's conduct was, at least partially, in accordance with the case law of the German courts; (b) at the time no EU case law existed concerned with cross-border mail services; and (c) DP had given an undertaking to introduce a procedure which would facilitate the detection of future infringements, should they occur: recital (193).

(7) Cases T-191/98 and T-212-214/98 *Atlantic Container Line v Commission*, EU:T:2003:245: there, fines had been imposed by the Commission on parties to the Trans-Atlantic Conference Agreement ("TACA") pursuant to the then regulation governing international maritime transport (Reg 4056/86) and, in part, the then regulation governing inland transport (Reg 1017/68), on the basis that certain provisions of the TACA concerning service contracts were contrary to Art 86. On appeal, the Court of First Instance held that since the TACA had been notified to the Commission for exemption, it was entitled to immunity from fines under Reg 4056/86. Although it had since been established that immunity did not similarly apply to a fine under Reg 1017/68, that accounted for only c. 5% of the fines imposed and the Court set aside the fines under that provision for several reasons, including the fact that the TACA had been notified voluntarily to the Commission and the applicants had thus on their own initiative revealed the position to the Commission; there was uncertainty at the time when TACA was notified whether notification granted immunity under Reg 1017/68 as well as under Reg 4056/86; the legal treatment of the practices of shipping conferences on service contracts was "not at all straightforward"; and conduct notified for individual exemption under Art 85(3) [now Art 101(3)] had not previously been subject to a fine for infringement of Art 86 [now Art 102]: judgment at paras 1597-1634.

(8) Case C-62/86 *Akzo v Commission*, EU:C:1991:286: this landmark judgment established the test for predatory pricing under Art 86 [now Art 102]. The Court of Justice upheld the infringement as "particularly

serious" but reduced the fine of 10 million ECU imposed by the Commission to 7.5 million ECU for three reasons: (a) competition law had not previously determined the rules applicable to abuses of that kind; (b) the infringement had very limited effect on the market shares of the relevant parties; and (c) the Commission had erroneously applied an aggravating factor in calculating the fine: para 163.

(9) Case Comp/E-2/37.857 *Organic Peroxides* (2003): This was a cartel decision where the participants in the cartel (other than the whistle-blower) received heavy fines. However, since addressing a cartel decision also to the company which performed only an organising and facilitating role for the cartel was a novelty, that company received only a nominal penalty: recital (454). The company's appeal, contending that the finding that it had infringed Article 81(1) [now Art 101(1)] was contrary the principle of legal certainty, was dismissed: Case T-99/04 *AC-Treuhand AG v Commission*, EU:T:2008:256.

141. It should be apparent from the above summaries that most of these cases are far removed from the present and provide neither precedent nor justification for not imposing penalties for the breach of the Chapter I prohibition (and Art 101(1) insofar as applicable to the GUK Agreement) in the present case. Given the nature of the Agreements, our conclusion on anti-competitive object and our finding that the parties cannot have been unaware of the Agreements' potential anti-competitive nature, we do not consider that the circumstances here can excuse the parties from fines (or justify only nominal fines).

142. We note also that the General Court upheld the imposition of very substantial fines by the Commission in its judgments in the *Lundbeck* cases,[15] which had many similar features to the present case albeit that there also were differences: see CAT Judgment at [310]-[318]. In *Ranbaxy* in particular, the Court rejected a similar argument based on novelty that relied on some of the same prior

[15] Lundbeck was fined over €93 million in total in respect of four agreements, including almost €20 million for the agreement concluded with GUK-Merck and close to €32 million for the agreement concluded with Alpharma. Merck was fined €21.4 million and GUK €7.8 million jointly and severally with Merck. Xellia and ALLC were fined jointly and severally €10.5 million.

judgments and decisions referred to above: see the judgment at paras 307-312; see also the judgment in *Merck* at para 520.

143. However, we think that the position is different as regards the Chapter II prohibition and the issue of GSK being in a dominant position. In that respect, we consider that there are some similarities with such decisions as *Italian Flat Glass* and *Deutsche Post*. The approach to market definition on which the CMA based its finding of dominance has been disapproved in the CAT Judgment; the approach set out by the CJEU is somewhat novel and was certainly not the standard means of assessment of the relevant market for pharmaceutical medicines in 2001-2002; and the further basis set out in the CAT Judgment (i.e. the constraint from PIs) had never been relied on by the CMA. Moreover, as regards the GUK and Alpharma Agreements, the violation of the Chapter II prohibition substantially overlaps with the violation of the Chapter I prohibition; the real significance of the finding under Chapter II is that it brings in the IVAX Agreement, which the CMA determined was exempt from the Chapter I Prohibition under the Exclusion Order.[16] Although that does not provide exemption from the Chapter II prohibition (see the CAT Judgment at [427]-[432]), we consider that this is a relevant factor when considering penalty. Taking account of all those factors together, we consider that the particular circumstances here mean that no penalty should be imposed on GSK for violation of the Chapter II prohibition.

Calculation of the penalties

144. The Tribunal has considered in a number of cases its role in a penalty appeal, including *Kier Group plc v OFT* [2011] CAT 3 (where the Tribunal cited passages from previous judgments of the Tribunal and the Court of Appeal) and *G F Tomlinson Group Ltd v OFT* [2011] CAT 7. In *Balmoral Tanks Ltd v CMA* [2017] CAT 23, the Tribunal (Rose J, as she then was, Dr Catherine Bell and Ms Margot Daly) stated, at [134]:

> "[…] the Tribunal has a full jurisdiction itself to assess the penalty to be imposed, particularly in view of the undertaking's right under Article 6(1) of

[16] CAT Judgment at [4(1)].

the European Convention on Human Rights to have the penalty reviewed afresh by an impartial and independent tribunal. The Tribunal's comments in *Kier* that it would not be right for the Tribunal to ignore the CMA's own approach and reasoning in the decision under challenge and that it should recognise a margin of appreciation afforded to the CMA in the application of its guidance are still relevant. The Tribunal in *Kier* clarified that the reference there to the CMA's margin of appreciation is not intended to restrict the intensity of the Tribunal's review of the penalty decision. Rather it indicates that "the Tribunal's role is not minutely to analyse each step of the Guidance but rather to consider the matter in the round, and on that basis, assess whether the final penalty is appropriate.": see paragraph 75 of *Kier*. The Tribunal went on:

> "76. The "margin of appreciation" to which the Tribunal there refers does not in any way impede or diminish the Tribunal's undoubted jurisdiction to reach its own independent view as to what is a just penalty in the light of all the relevant factors. In these circumstances any debate about the scope of any margin of appreciation becomes somewhat sterile. The Guidance reflects the OFT's chosen methodology for exercising its power to penalise infringements. It is expressed in relatively wide and non-specific language, which is open to interpretation, and which is clearly designed to leave the OFT sufficient flexibility to apply its provisions in many different situations. Provided the penalty ultimately arrived at is, in the Tribunal's view, appropriate it will rarely serve much purpose to examine minutely the way in which the OFT interpreted and applied the Guidance at each specific step. As the Tribunal said in Argos (above), the Guidance allows scope for adjusting at later stages a penalty which viewed in isolation at an earlier, provisional, stage might appear too high or too low.
>
> 77. On the other hand if, as in all the Present Appeals, the ultimate penalty appears to be excessive it will be important for the Tribunal to investigate and identify at which stage of the OFT's process error has crept in. Assuming the Guidance itself is unimpugned (and in the Present Appeals there has been no attack on it), the imposition of an excessive or unjust penalty is likely to reflect some misapplication or misinterpretation of the Guidance." "

145. The Tribunal proceeded to quote and adopt the following passage from the judgment in *Tomlinson Group*:

> "72 … In our judgment, the Tribunal's task is two-fold. The grounds of appeal pleaded by the Present Appellants raise a number of specific complaints about particular steps taken by the OFT in computing the fines imposed in the Decision. Part of our task is therefore to adjudicate on those specific complaints since it is important for the OFT and the parties to know where, if anywhere, we judge that the OFT has gone wrong in applying the Guidance in this case. But the other part of our task is, as the OFT accepts, to look at the matter in the round and form our own view about the appropriateness of the penalties imposed."

146. Accordingly, we address the steps taken by the CMA in applying the Penalty Guidance and the particular challenges made by the various Appellants, before considering the penalties in the round.

Step 1: the starting point

147. The starting point is calculated having regard to the seriousness of the infringement and the undertaking's relevant turnover: Penalty Guidance, para 11.24. All the Appellants challenge the percentage applied for seriousness and both GSK and Merck challenge the CMA's approach to relevant turnover.

Seriousness

148. The Penalty Guidance states that price-fixing or market-sharing agreements and other cartel activities are among the most serious infringements of the Chapter I prohibition and/or Art 101, and provides that the maximum percentage applied for seriousness under step 1 is 30%: paras 2.4-2.5. The Guidance explains, at para 2.6:

> "… When making its assessment, the [CMA] will consider a number of factors, including the nature of the product, the structure of the market, the market share(s) of the undertaking(s) involved in the infringement, entry conditions and the effect on competitors and third parties. The seriousness assessment will also take into account the need to deter other undertakings from engaging in such infringements in the future. The damage caused to consumers whether directly or indirectly will also be an important consideration. The assessment will be made on a case-by-case basis for all types of infringement, taking account of all the circumstances of the case."

149. Here, the CMA applied a percentage of 21% on the basis that each infringement was serious in nature. That determination was based on a number of factors: Decision, paras 11.26-11.27. Those included:

(1) each of the Agreements was a horizontal agreement involving payments from an incumbent to potential competitors with the purpose of delaying the threat of their potential market entry, which had the object and/or effect of restricting competition in the supply of paroxetine in the UK;

(2) the relevant market concerned the nationwide supply of paroxetine, a widely prescribed antidepressant medicine which had generated sales for GSK of £91 million in 2001;

(3) GUK and Alpharma agreed to defer their efforts to enter the market and challenge GSK's patents only on being compensated by substantial value transfers;

(4) The likely effect of the infringements was to defer the threat of true generic competition, which typically results in significant decreases in the prices paid by pharmacies and, ultimately, the NHS.

150. The Appellants contend that a figure of 21% is much too high, pointing to decisions where an equivalent figure (20-22%) was used for hard-core cartels. They stress that the Agreements here involved the introduction of generic paroxetine into the UK market. GUK asserts that the Agreements "introduced more competition than previously existed on the market": Notice of Appeal, para 10.2. The Appellants further rely on the novelty at the time of finding that such patent settlement agreements could infringe competition law.

151. We consider that very limited assistance in this regard can be obtained from previous OFT and CMA decisions, since seriousness depends on a number of factors and each case is very different. Thus as regards two previous decisions on which several of the Appellants rely, *Care home medicines* (decision of 20 March 2014) applied a starting point of 22% for market-sharing in a small part of a market that was highly fragmented, with many other competitors (see at para 7.23); and *Access control and alarms* (decision of 6 December 2013), applied a starting point of 20% for each of the three infringements which concerned collusive tendering in respect of a limited number of contracts for retirement homes run by one particular manager of retirement properties in the UK.

152. For reasons set out in the CAT Judgment and repeated above, we do not accept that the Agreements introduced meaningful competition into the market (other than to a limited extent with PIs). On the contrary, the Agreements had the object of protecting GSK from the risk of the very significant competition that would have occurred if GUK and/or Alpharma had pursued their patent challenges and been successful in the near future. However, since the outcome of the patent trials was uncertain, it cannot be said that a proper comparison is

the fully 'genericised' price. The reality was that the parties were engaged in patent litigation in which GUK and Alpharma had a serious prospect of success. In our view, the notional 'competitive' price at the time of the Agreements was therefore a price which reflected that prospect: it would be somewhere on the spectrum between the higher monopoly price[17] and the genericised price. The size of the value transfers from GSK to, respectively, GUK and Alpharma, under each of their Agreements reflected the parties' assessment and compromise regarding that prospect. But it was in the nature of the Agreements that the price charged to consumers was maintained at almost the pre-existing level, with the resulting profit shared between GSK and the two generic companies. We consider that this is the real mischief of the Agreements. As regards consumers (and in particular the NHS), the Agreements were very different from, for example, a patent settlement in terms of a licence to the generic company to enter before the expiry of the patent. The extent of such a licence would also reflect the parties' assessment and compromise regarding the strength of the patent; but under a settlement of that kind, by allowing full generic entry earlier, the compromise would feed through into the price charged to consumers.

153. Although we do not disapprove the other observations on seriousness set out in the Decision, we therefore approach this question on a somewhat different basis in concluding that these were serious infringements. We recognise that a percentage of 21% is on the high side. But in light of the matters set out and discussed above, we do not think that it falls outside the CMA's margin of appreciation and, accordingly, we do not think that it is an error such that it would be appropriate for the Tribunal to vary it. The question of mitigation, having regard to novelty and what could have been expected at the time, can be taken into account at various stages of the penalty assessment and here we think that it can be appropriately addressed at Step 4.

Relevant turnover

154. As the Tribunal stated in *Eden Brown v OFT* [2011] CAT 8 at [44]:

[17] See paras 35-36 above.

> "relevant turnover is used to reflect the effective scale of activity of each undertaking."

The Penalty Guidance explains that the relevant turnover is the turnover of the undertaking in the relevant market affected by the infringement in the undertaking's last financial year preceding the date when the infringement ended: para 2.7. But the Guidance continues, at para 2.8:

> "Generally, the OFT will base relevant turnover on figures from an undertaking's audited accounts. However, in exceptional circumstances it may be appropriate to use a different figure as reflecting the true scale of an undertaking's activities in the relevant market."

Para 2.8 cites [44]-[59] of *Eden Brown* as authority for that proposition.

155. The CMA specified GSK's relevant turnover for the purpose of the Chapter I prohibition/Art 101 as £67,122,000. This corresponds to GSK's total sales of paroxetine in its financial year ended 31 December 2003, after the deduction of sales rebates, VAT and other turnover-related taxes: Decision, paras 11.32, 11.34.

156. On the same basis, the relevant turnover of GUK-Merck and Alpharma would be £8,132,276 and £4,328,620 respectively. However, the Decision states, at para 11.35:

> "The CMA considers that the net sales set out at paragraphs 11.34(c) and 11.34(d) do not, on their own, reflect the true scale of income that GUK and Alpharma derived from supplying paroxetine in the UK. This is because in the financial year ended 31 December 2003 GUK and Alpharma each received, under the Infringing Agreements, other income – namely, certain cash payments from GSK (whether directly or indirectly via IVAX). This additional income was directly linked to, and was a significant part of the revenue received by, GUK and Alpharma in relation to their activities on the relevant market. The CMA considers that any calculation of relevant turnover which did not include this other income would not reflect the true scale of each of those undertaking's activities in the relevant market, and would not be an appropriate measure of the scale and impact of the infringing activity in which each of GUK and Alpharma was engaged." [footnotes omitted]

157. Accordingly, the CMA added to the net sales figures the various payments made to GUK and Alpharma under their Agreements in the financial year ended 31 December 2003. As a result, the relevant turnover for GUK-Merck was

calculated to be £13,013,169, and the relevant turnover for Alpharma was calculated to be £5,728,620: Decision, paras 11.36-11.37.

158. GSK challenges the determination of its relevant turnover on the basis that "the CMA's approach to the calculation of market share" was flawed on two grounds:

(1) it was inconsistent, since the CMA found that under the infringements GSK "shared its supra-competitive profits with GUK and Alpharma through the value transfers" under the Agreements, but then did not take account of that sharing of profits when calculating GSK's relevant turnover; and

(2) it was discriminatory since the sums originating from GSK treated as income in the hands of GUK-Merck and Alpharma were not netted off against GSK's turnover.

159. We regard GSK's criticisms as misconceived. Relevant turnover for this purpose is not intended as a market share calculation but, as noted above, a figure designed to reflect the scale of the undertaking's activity in the market and thus to be used in arriving at the starting point for a penalty. The figure used for GSK corresponds to its net sales of paroxetine. In our judgment, there is no justification for reducing that net sales figure on the ground that GSK shared its high profits by making payments to competitors under agreements that infringed competition law. Nor is there any discrimination against GSK in this approach: GUK and Alpharma were in an objectively different position.

160. We should add that insofar as the CMA sought to justify its approach by reference to the Competition Act 1998 (Determination of Turnover Penalties) Order 2000 (the "2000 Order"), we do not think that is relevant. The 2000 Order is concerned with the definition of turnover for the purpose of the 'cap' in s. 36(8) CA, which is a different matter from the "relevant turnover" for the purpose of step 1 of the Penalty Guidance.

161. Merck (but not GUK) challenges the increase in its relevant turnover by the addition of the other payments made to GUK under the GUK Agreement, on the basis that these were not "exceptional circumstances" within the terms of para 2.8 of the Penalty Guidance. The notion of "exceptional" is clearly intended to cover a case where relevant sales revenue alone does not reflect the scale of relevant activity and we consider that the CMA was fully entitled to come to the view that the additional sums were in reality part of the revenue of GUK (and Alpharma) relating to their activities on the UK paroxetine market. Were it otherwise, where company A paid company B a large sum to keep out of a market altogether, the position would be that company B had no relevant turnover in the products affected by the infringement and would escape any penalty. We note that neither Actavis nor Xellia/ALLC sought to advance a similar argument as regards the relevant turnover of Alpharma.

Step 2: duration

162. Penalties for infringements that last more than one year may be multiplied by the number of years of the infringement. For that purpose, the CMA will normally round up part years to the nearest quarter year but in exceptional cases it may round up the part year to a full year: Penalty Guidance, para 2.12.

163. Here, the CMA calculated the multipliers for duration as follows for the Chapter I prohibition/Article 101:

Infringement	**Infringement start and end dates**	**Infringement duration**	**Multiplier to step 1 figure**
GUK-GSK Agreement	13 March 2002 – 1 July 2004	2 years, 3 months and 18 days	2.5
Alpharma-GSK Agreement	12 November 2002 – 13 February 2004	1 year, 3 months and 1 day	1.5

164. GSK and Actavis challenge the relevant multipliers for duration.

165. GSK relies on two grounds:

(1) The interim injunction against GUK and the undertaking given by Alpharma in lieu of an injunction prevented GUK and Alpharma from entering the market in any event at the time of their respective Agreements;

(2) GSK's patent was revoked in the Apotex litigation in December 2003 and the CMA had accepted that the likely effects of the Agreements extended no further than 30 November 2003.

166. However, step 2 relates simply to the duration of the infringing agreement (or conduct) itself. It does not involve an assessment of the effect of the infringement, which in some cases might indeed continue to have an effect after an infringing agreement had been brought to an end. For example, it is not unusual that prices which are raised as the result of a cartel do not return to competitive levels immediately when a cartel comes to an end. Step 2 does not introduce such a potentially complicated assessment of effects. Here, the infringements comprised the GUK and Alpharma Agreements and the dates of those Agreements are correctly reflected in the start dates for the purpose of duration.

167. As to the end dates, although the market was indeed open to generic entry from December 2003 following the Apotex judgment,[18] neither Alpharma nor GUK were free to enter the market at that point because of the terms of their respective Agreements. Under the Alpharma Agreement, Alpharma had to give a month's notice, which it did on 13 January 2004 so the Alpharma Agreement came to an end on 13 February 2004. The restriction in the GUK Agreement remained in force until GUK could terminate the related IVAX-GUK Supply Agreement. As a result, the GUK Agreement was brought to an end only on 1 July 2004: CAT Judgment at [52]. The end dates applied by the CMA are accordingly correct.

[18] It is not clear to us why the CMA stated that the likely effect of the infringing agreements would have ceased by 30 November 2003. Judgment in the Apotex litigation was given on 5 December 2003 and Neolab and Waymade entered the market about two weeks later: Decision, Table 3.1 and CAT Judgment at [50]. In any event, both Alpharma and GUK were still prevented from entering by the restrictions on terminating their respective agreements.

168. Actavis raises a separate point that the start date for its infringement should be 20 November 2002 (i.e. eight days later) when it entered into the Alpharma-IVAX Agreement, since it was only then that the Alpharma Agreement became legally binding. However, as the CMA points out in its Defence, an agreement for the purpose of the Chapter I prohibition does not have to be legally binding. An "agreement" for the purpose of competition law requires a concurrence of wills, and as between Alpharma and GSK that occurred on 12 November 2002 when they agreed in writing to settle the Alpharma litigation on terms that compensated Alpharma for not entering the market independently of GSK. The subsequent signature of the Alpharma-IVAX Agreement was in implementation of that Alpharma Agreement.

169. As regards the end date, Alpharma gave one month's notice terminating the Alpharma-IVAX agreement on 13 January 2004. Actavis contends that the Alpharma Agreement therefore terminated on 12 not 13 February 2004 (which could reduce its rounded duration to 1.25). This point, put forward in one sentence within para 181(b) of its Notice of Appeal, is not addressed in the CMA's Defence and was not the subject of further argument. However, where a contract provides for termination on one month's notice, in the absence of contrary provision English law applies the corresponding date rule and it will terminate on the same date of the following month: see Lewison, *The Interpretation of Contracts* (6th edn, 2015), para 15.04.

Step 3: aggravating and mitigating factors

170. The CMA held that there were no aggravating factors: Decision, para 11.42.

171. As regards mitigation, the CMA considered that Merck, Actavis and each of Xellia and ALLC provided voluntary cooperation which enabled the investigation to be concluded "more effectively and/or speedily". As a result, a 5% reduction for cooperation was applied at Step 3 for each of those Appellants: Decision, paras 11.47-11.49.

172. GSK alone challenges the Decision as regards the application of Step 3. First, it asserts that it too should have received a discount for enabling the enforcement

process to be concluded more effectively and speedily on the basis that it answered all the CMA's s. 26 requests comprehensively; responded fully and timeously to three letters of fact; provided timeous and conscientious disclosure; and participated in multiple meetings and oral hearings with the CMA.

173. We regard that argument as fundamentally misconceived. In Case C-293/13 P *Fresh Del Monte v Commission*, EU:C:2014:2439, Kokott AG stated in her Opinion, at para 241:

> "The existence of mitigating factors can by no means be concluded from the absence of such aggravating circumstances. A party wishing to benefit from mitigating circumstances must do more than adopt the normal conduct which may be reasonably expected of any party to the proceedings. It must put all its cards on the table on its own initiative."

174. As the CMA observes in its Defence, GSK did no more than what would be expected of any undertaking during an administrative procedure: i.e., responding to s. 26 notices, attending meetings and an oral hearing, and commenting on letters of fact. Moreover, the Decision records that GSK refused nine requests made by the OFT at various points in 2012 and 2014 to make GSK staff voluntarily available for interview: para K.32. We consider that the CMA was fully entitled to conclude that, unlike Merck, Actavis, Xellia and ALLC, GSK did not provide voluntary cooperation amounting to a mitigating factor as regards the penalty to be imposed.

175. GSK further alleges that the CMA viewed mitigation too narrowly, referring to the inclusion in the non-exhaustive list of mitigating factors in the Penalty Guidance at para 2.15 of:

> "genuine uncertainty on the part of the undertaking as to whether the agreement or conduct constituted an infringement".

GSK argues that accordingly credit should have been given under step 3 on this basis.

176. We think that there is some force in this point, but as noted above there is a degree of overlap between the various considerations that can be taken into account under the individual steps of the Penalty Guidance. We consider that the novelty of the infringement was a factor that should be reflected in

calculation of the penalty but the CMA addressed this aspect under Step 4. In our view, that was not in itself an error: the important point is that it should be addressed and what matters is the overall calculation which results.

Step 4: deterrence and proportionality

177. The Penalty Guidance explains that under this step the figure reached after steps 1-3 may be increased to ensure that the penalty imposed will deter the undertaking from future breach of competition law, having regard to its size and financial position and "any other relevant circumstances of the case". Moreover, the overall penalty will then be considered in the round, to ensure that it is not disproportionate or excessive. As regards this assessment of proportionality, regard will be had to:

> "the undertaking's size and financial position, the nature of the infringement, the role of the undertaking in the infringement and the impact of the undertaking's infringing activity on competition." (para 2.20)

178. In the Decision, the CMA, in our view correctly, considered the question of adjustment under step 4 separately as regards the penalties of all addressees of the Decision and then as regards the penalty on each specific addressee.

179. As regards the penalties on all the addressees (i.e. all the Appellants), it was under this head that the CMA considered the questions of novelty and the lapse of time between the infringements and the start of the investigation. Since the CMA's approach is strongly criticised by all the Appellants, it is appropriate to set out the paragraphs in which the CMA addressed those matters:

> "11.54 When assessing whether any penalty in this case would be appropriate in the round, the CMA has had regard to its view that the Infringements were serious in nature, and that there is no basis for differentiating between the respective roles of GSK, GUK and Alpharma in the Infringements, as noted under 'Seriousness' at Step 1 above. The CMA has also had regard to the considerations set out at paragraphs 11.55 to 11.60.
>
> 11.55 The CMA finds that the purpose of the Infringements was to defer the threat of true generic competition. Substantial gains can be made from deferring the full development of true generic competition in the pharmaceutical sector, since such competition can, in general, result in significant price decreases. This is demonstrated by the examples set out at paragraphs 3.62 and 6.36. In addition, in this case, Seroxat prices

fell by around 60% within two years of the emergence of true generic competition (following Apotex's entry); moreover, such a fall was consistent with the Parties' expectations of the likely impact of true generic competition in the UK paroxetine market.

11.56 As such, sustaining substantially higher pharmaceutical prices, via so-called 'pay for delay' arrangements, enables both the participating originators and generic suppliers to realise significant financial gains through sharing the relevant originator's monopoly profits (which are at levels far higher than would exist after the emergence of true generic competition), at the expense of the NHS. In this case, for example, GSK made profits on its sales of Seroxat of £46.3 million in 2001 (that is, prior to the Infringements) and these had fallen to £5.8 million by 2005 (after the emergence of true generic competition).

11.57 Given the relevant circumstances of this case set out at paragraphs 11.55 to 11.56, the CMA has reflected on whether the penalty figures reached after steps 1 to 3 should be increased, in order to ensure that the penalties imposed in this case would deter the Parties from infringing competition law in the future.

11.58 However, the CMA notes that at the time of the Infringements there had been no finding that this specific form of anti-competitive agreements (so-called 'pay for delay' agreements) infringed the Chapter I prohibition, Article 101 TFEU, the Chapter II prohibition or Article 102 TFEU, although it was already well established that excluding actual or potential competitors from the market was likely to infringe competition law. The CMA has taken this into account in the round when calculating penalties in this case.

11.59 In addition, the CMA is mindful of the passage of time between the Relevant Period and the launch of this Investigation. While each Party has been able to identify and provide a substantial volume of contemporaneous evidence relevant to the Investigation (and in many instances, relevant witnesses have given evidence to the OFT/CMA), the CMA recognises that, given the passage of time, searching for contemporaneous evidence and/or data relevant to this Investigation may have involved an increased administrative burden for the Parties.

11.60 Having assessed the relevant circumstances set out at paragraphs 11.55 to 11.59, in the specific circumstances of this case the CMA considers that:

(a) no further uplift should be made, to the penalty for any Party, in order to achieve specific deterrence on the basis of the relevant circumstances set out at paragraphs 11.55 to 11.56; and

(b) it is appropriate, considering the factors in the round, to apply a 10% reduction of the penalty for each Party reached at the end of steps 1 to 3, in order to reach an appropriate penalty for each Party.

11.61 It is entirely possible that in future similar cases where parties have significant turnover outside the relevant market and/or substantial gains would likely be made given the relevant circumstances set out at paragraphs 11.55 to

> 11.56, the CMA may consider that penalties should be increased at this step of a penalty calculation in order to achieve specific deterrence."

180. We acknowledge that the CMA has a margin of appreciation when it comes to determination of penalty. Nonetheless, we conclude that the approach adopted in these paragraphs, and thus the application of step 4 in this case, was flawed.

181. As the CMA recognises, at the time of the Agreements there had been no finding that patent settlement agreements of this kind infringed EU or UK competition law. Even in the United States, notwithstanding the high profile of the antitrust laws and the vigorous climate of private enforcement in that jurisdiction, there had been at that time few decisions that such agreements gave rise to an antitrust violation[19] and the law remained in a state of uncertainty until the US Supreme Court judgment in *FTC v Actavis Inc*, 570 US 136 (2013). Moreover, although para 11.55 of the Decision, quoted above, describes the purpose of the Agreements as to defer "the *threat* of true generic competition", para 11.56 proceeds to consider the effect of such arrangements as enabling the originator (i.e. GSK) to "realise significant financial gains", comparing the profits achieved while patent protection remained with the dramatically lower prices after full generic competition. But that ignores the critical fact that the strength of the patents at the material time was uncertain. The primary role of patents is to reward and incentivise innovation by the legitimate exclusion of competitors, enabling the patentee to maintain prices well above those which would pertain in a market open to direct competition in the formerly patented product. As discussed at para 152 above, we accordingly, consider that the "competitive" price of a patented pharmaceutical product will be high when the patent is secure, low after full generic entry, and falling on an uncertain path from high to low in the period when the patent is uncertain and generic companies are seeking to enter the market.

182. As regards deterrence, in our view the CMA was clearly right to hold that no uplift for deterrence is appropriate in this case. However, insofar as the paragraphs quoted suggest that deterrence was taken into account in fixing the

[19] One such decision was *Andrx Pharms, Inc v Biovail Corp Int'l*, 256 F 3d 799 (DC Cir, 2001). However, various Federal Courts of Appeal took different views: see the judgment of Breyer J in *Actavis.*

reduction of 10% as opposed to a higher figure, we think that would be an error. That the CMA did consider a need for deterrence is indicated by its repeated reference to this in its subsequent assessment of the proportionality of the individual penalties: see Decision, paras 11.68, 11.75, 11.80, 11.83 and 11.85. But aside from the important point about novelty, there is no suggestion that any of the parties, who are all active in the supply of pharmaceutical drugs, have entered into further agreements of this kind in the 4½ years between the opening of the investigation by the OFT in August 2011 and the Decision (or indeed since). We note that the CMA states that in a future similar case it may consider increasing the penalty to achieve deterrence. But in such a future case, the companies will have the precedent of the present case, whereas at the time of the Agreements here at issue there was no analogous decision.

183. Moreover, in our view the CMA failed also to reflect sufficiently the effect of the very substantial passage of time between the infringing arrangements (2001-2002) and the start of the investigation. We think this imposed a significant additional burden on the Appellants in what was in any event a complex case. The CMA's Defence appears to treat the arguments raised on this basis in terms of an alleged infringement of the rights of the defence. However, although the substance is obviously related, the point is distinct. We have already dismissed grounds of appeal alleging that the rights of defence were infringed: CAT Judgment at [433]-[441]. Such an allegation, if substantiated, can be a basis for setting a decision aside. Here, the question is the less hard-edged issue of whether on proportionality grounds this delay and its consequences should lead to lower penalties. We consider that the delay caused very real practical problems for GSK in the investigation in seeking to retrieve and then reconcile data from different and historic financial databases. As regards Xellia and ALLC, we note further that although the OFT launched its investigation in August 2011, that investigation was not extended to cover those companies until March 2013, over 10 years after the Alpharma Agreement had been entered into. It is unsurprising that they therefore no longer had access to many relevant documents. And for all the Appellants, the substantial lapse of time inevitably affected the recollection of relevant witnesses.

184. Merck argues that it should have received a higher step 4 reduction on the basis that it had sold its interest in GUK in 2007, several years before the start of the investigation which, it said, led it to face difficulties in responding to the investigation that were "more acute for Merck than for the other addressees". We do not accept that particular submission. The position in that regard is analogous to that of Actavis, which is an addressee of the Decision because it acquired Alpharma as part of the assets of Alpharma Inc in December 2005, but not Alpharma Inc itself and therefore had no direct access to many of the employees and documents of Alpharma's paroxetine business which derived from its parent company. Further, in mid-2006 a warehouse fire had destroyed many of the documents from the Alpharma patent litigation. In the CAT Judgment, addressing the argument of Actavis, we stated at [438] that we did not think that there could have been any complaint about delay if the investigation had started only at the end of 2006, and we take the same view if it had started only at the end of 2007. We also note that it is not unusual on a corporate sale of this scale for the vendor to require the purchaser to provide reasonable assistance in the event that the vendor faces legal proceedings regarding an activity of the business carried out prior to its sale.

185. Accordingly, while we consider that the lapse of time is a very relevant factor as regards all the Appellants, we do not consider that Merck (or Actavis) are in a special category. We should add that we do not regard the time spent on the investigation itself as relevant to proportionality. Although that time was considerable (4½ years between the opening of the investigation and the Decision), that in part reflects the unusual complexity of this case, the practical difficulties caused by the delay to which we refer above, and we have little doubt also the volume of submissions and argument addressed by the various parties during the administrative procedure. We should also emphasise that delay in the launch of an investigation will not go to reduce the level of penalty in all cases: e.g., in the case of a secret cartel, the parties often go to considerable lengths to prevent their unlawful arrangements from being discovered. But in the present case, although the terms of the Agreements were confidential, the fact that the parties had settled their respective patent proceedings was a matter of record

and there was nothing covert about the supply by, first, GUK and then Alpharma of generic paroxetine obtained from GSK.

186. Taking account of all the above factors in the manner discussed, we think that as a matter of proportionality an overall reduction of 10% is much too low. The appropriate level of reduction is inevitably an evaluative assessment and not a matter of precise calculation. In our judgment, the correct reduction in this case, for all Appellants, is 40%.

187. Turning to the proportionality assessments for each individual party, as regards GSK's Chapter I/Art 101 penalties, the figures resulting from the CMA's approach were:

(1) £31,715,145 in respect of the GUK Agreement; and

(2) £19,029,087 in respect of the Alpharma Agreement.

188. The CMA held that it was appropriate to calculate a separate penalty in respect of each infringing Agreement but that an aggregate penalty resulting from the above figures of £50,744,232 would be disproportionate, given the overlaps in the product market, geographic area and time periods as between the two Agreements, as well as the proportion which this would represent of various financial indicators for GSK. The CMA therefore reduced the penalty calculated for the Alpharma Agreement at the end of step 3 by 85%. With the further reduction at step 4 of 10%, this reduced the separate penalty for the Alpharma Agreement at the end of step 3 by 95% to £1,057,172.[20]

189. GSK submits that separate penalties should not be imposed for the two Agreements; and that in any event, there was no reason to apply the 85% reduction to the smaller penalty for the Alpharma Agreement whereas a substantially lower overall penalty would result if that reduction were applied to the penalty for the GUK Agreement.

[20] See the Decision at Annex P, table P.1.

190. We reject those submissions. In the end, it does not matter whether the overall figure is approached by aggregating separate figures calculated for each Agreement or by calculating one figure for both Agreements: it is the level of the overall figure that counts. In our view, the fact that GSK entered into two distinct infringing Agreements, almost eight months apart and with different generic companies, manifestly justifies a significantly higher penalty than if GSK had entered into only one of those Agreements. We see nothing wrong with the CMA's approach of calculating separate figures and then adjusting one of them because of the excessive effect of a simple aggregation of the two. Secondly, we consider that the application of the 85% reduction to the Alpharma Agreement as opposed to the GUK Agreement is logical and appropriate. The GUK Agreement lasted significantly longer, not only because it was made earlier but because it contained a provision (through the linked IVAX-GUK Supply Agreement) which prevented immediate termination once generic entry occurred: CAT Judgment at [52]. The duration of the Alpharma Agreement was accordingly encompassed within the more extended duration of the GUK Agreement.

191. However, because we have substituted a 40% reduction at step 4 for the CMA's 10%, applying a further 85% reduction to the separate penalty for the Alpharma Agreement at the end of step 3 would produce a 125% reduction. We consider that an overall reduction of 95%, as applied by the CMA, is appropriate and accordingly apply a reduction of 55% at the end of step 3.

192. Since we have set aside the decision to impose a penalty on GSK as regards the Chapter II prohibition, it is unnecessary to address GSK's submissions regarding the calculation of that penalty.

193. As regards GUK, the penalty calculated by the CMA on the basis set out above (i.e. steps 1-3 and then a 10% reduction) was £6,148,722. The CMA regarded that as disproportionate because it would amount, inter alia, to 8.8% of GUK's average worldwide turnover and 149.3% of its average annual post-tax profits in its last three financial years. Therefore, the CMA stated that it reduced the penalty on GUK by 50% to £2,732,765: Decision, para 11.75. In fact, that figure is arrived at by reducing the calculation at the end of step 3 by 50%, and then

applying the further, general 10% reduction, i.e. a total reduction of 60%: see Table P.2 in the Decision at Annex P.

194. Since we have substituted a 40% reduction in step 4, that would produce a penalty of £4,099,168. We consider that it is appropriate to apply the 50% reduction to that final figure since that is in our view the relevant comparator to GUK's financial performance. That accordingly results in a penalty of £2,049,574.

195. As regards Merck, the penalty calculated by the CMA on the above basis of £5,841,286 represented 0.06% of Merck's average annual worldwide turnover and 0.72% of its average annual post-tax profits in the its last three financial years. Having regard to Merck's size and financial position, the CMA made no reduction to Merck's penalty. Merck submits that this amounted to an error of law on the basis that the CMA was not entitled to impose a greater penalty on Merck than on GUK. Merck argued that since it was not directly involved in the infringement and its liability was based on its 100% indirect ownership of GUK at the time of the GUK Agreement, its liability as a parent company cannot exceed that of its subsidiary which directly committed the infringement.

196. For this proposition, Merck relied on Case C-597/13 P *Total SA v Commission*, EU:C:2015:613. However, as the CMA points out in its Defence, in that case the CJEU held that the *liability* of a parent cannot exceed that of its subsidiary when the parent's liability derives from the exercise of decisive influence over the subsidiary. There, the fine on Total SA's French subsidiary had been reduced on account of duration (i.e. the way the Commission had calculated the duration of the infringement was found to be flawed); it followed that the fine levied on Total SA required equivalent adjustment. Thus, the CMA here could not assign a higher seriousness percentage or apply a higher multiplier for duration for Merck than for GUK. That principle is quite different from the question of assessing the proportionality of the penalty under step 4, having regard to the size and financial position of each of the companies at the time of the decision. When the former subsidiary is no longer under the same ownership, it is particularly important that this assessment is carried out

separately for each. That is what the CMA did and we find that there was no error of law.

197. The CMA made no individual adjustments to the penalties calculated on the above basis as regards Actavis, Xellia or ALLC. No particular points are taken in that regard in their respective appeals (save as regards delay, discussed above).

Step 5: adjustment to prevent the maximum penalty being exceeded; Step 6: reductions for leniency and settlement

198. None of the penalties calculated exceeded the statutory maximum so no adjustment under step 5 was required. Step 6 did not apply.

Consideration of the penalties overall

199. Applying the higher reduction under step 4, the recalculated individual penalties are as follows:

GSK	£22,200,602
GUK-Merck: total penalty	£3,894,191 for which:
- Merck is liable for	£3,894,191
- GUK is jointly and severally liable for	£2,049,574
Alpharma: total penalty	£1,028,574 for which
- Actavis, Xellia and ALLC are jointly and severally liable	

The detailed calculations are set out in Appendix 2.

200. Standing back, we have considered each of the figures set out above in the round. For serious infringements committed by large and sophisticated

companies, concerning a major pharmaceutical drug, with the potential to cause significant financial harm to the UK public health authorities, in our judgment these penalties are not inappropriate or unjust as regards any of the Appellants.

H. CONCLUSION

201. For the reasons set out above:

(1) the outstanding grounds in each of the appeals against liability are dismissed;

(2) GSK's appeal as regards the imposition of a penalty for breach of the Chapter II prohibition is allowed;

(3) all the appeals against penalty for breach of the Chapter I prohibition (and of Art 101(1) as regards the GUK Agreement) are allowed to the extent that for the penalties imposed we substitute the following penalties:

(a) on GSK: £22,200,602

(b) on GUK-Merck: £3,894,191:

(i) of which Merck is liable for £3,894,191; and

(ii) GUK is jointly and severally liable for £2,049,574

(c) on Alpharma: £1,028,574:

(i) Actavis is jointly and severally liable for £1,028,574;

(ii) Xellia is jointly and severally liable for £1,028,574; and

(iii) Alpharma is jointly and severally liable for £1,028,574.

202. This judgment is unanimous.

Mr Justice Roth
President

Dermot Glynn

Hodge Malek QC

Charles Dhanowa O.B.E, Q.C. (*Hon)*
Registrar

Date: 10 May 2021

APPENDIX 1

QUESTIONS REFFERED TO THE CJEU

(1) Potential competition

For the purpose of Article 101(1) [TFEU], are the holder of a patent for a pharmaceutical drug and a generic company seeking to enter the market with a generic version of the drug to be regarded as potential competitors when the parties are in bona fide dispute as to whether the patent is valid and/or the generic product infringes the patent?

(2) Does the answer to Question 1 differ if:

(a) there are pending court proceedings between the parties involving this dispute; and/or

(b) the patent-holder has obtained an interim injunction preventing the generic company

(c) from launching its generic product on the market until determination of those proceedings; and/or

(d) the patent holder regards the generic company as a potential competitor?

(3) Restriction by object

When there are pending court proceedings concerning the validity of a patent for a pharmaceutical drug and whether a generic product infringes that patent, and it is not possible to determine the likelihood of either party succeeding in those proceedings, is there a restriction of competition "by object" for the purpose of Article 101(1) [TFEU] when the parties make an agreement to settle that litigation whereby:

(a) the generic company agrees not to enter the market with its generic product and not to continue its challenge to the patent for the duration of the agreement (which is no longer than the unexpired period of the patent), and

(b) the patent holder agrees to make a transfer of value to the generic company in an amount substantially greater than the avoided litigation costs (including management time and disruption) and which does not constitute payment for any goods or services supplied to the patent holder?

(4) Does the answer to Question 3 differ if:

(a) the scope of the restriction on the generic company does not go beyond the scope of the patent in dispute; and/or

(b) the amount of the value transfer to the generic company may be less than the profit it would have made if it had instead succeeded in the patent litigation and entered the market with an independent generic product?

(5) Do the answers to Questions 3 and 4 differ if the agreement provides for the supply by the patent holder to the generic company of significant but limited volumes of authorised generic product and that agreement:

(a) does not give rise to any meaningful competitive constraint on the prices charged by the patent holder; but

(b) brings some benefits to consumers which would not have occurred if the patent holder had succeeded in the litigation, but which are significantly less than the full competitive benefits resulting from independent generic entry which would have occurred if the generic company had succeeded in the litigation, or is this relevant only to assessment under Article 101(3) [TFEU]?

(6) Restriction by effect

In the circumstances set out in Questions 3-5, is there a restriction of competition "by effect" for the purpose of Article 101(1) [TFEU] or does that depend upon the court finding that in the absence of that settlement:

(a) the generic company would probably have succeeded in the patent proceedings (i.e. that the chance that the patent was valid and infringed was below 50%); alternatively

(b) the parties would probably have entered into a less restrictive settlement (i.e. that the chance of a less restrictive settlement was above 50%)?

(7) Market definition

Where a patented pharmaceutical drug is therapeutically substitutable with a number of other drugs in a class, and the alleged abuse for the purpose of Article 102 [TFEU] is conduct by the patent holder that effectively excludes generic versions of that drug from the market, are those generic products to be taken into account for the purpose of defining the relevant product market, although they could not lawfully enter the market before expiry of the patent if (which is uncertain) the patent is valid and infringed by those generic products?

(8) Abuse

In the circumstances set out in Questions 3-5 above, if the patent holder is in a dominant position, does its conduct in entering into such an agreement constitute an abuse within the meaning of Article 102 [TFEU]?

(9) Does the answer to Question 8 differ if the patent holder makes an agreement of that kind not in settlement of actual litigation but to avoid litigation being commenced?

(10) Does the answer to Question 8 or 9 differ if:

(a) the patent holder pursues a strategy of entering into several such agreements to preclude the risk of unrestricted generic entry; and

(b) the consequence of the first such agreement is that by reason of the structure of the national arrangements for reimbursement by the public health authorities to pharmacies of their costs of purchasing pharmaceutical drugs, the reimbursement level for the pharmaceutical drug in question is reduced, resulting in a substantial saving to the public health authorities (albeit a saving which is significantly less than that which would arise upon independent generic entry following a successful outcome for the generic company in patent litigation); and

(c) that saving was no part of the intention of the parties when entering into any of the agreements?

APPENDIX 2

TABLES SHOWING PENALTY CALCULATIONS

GSK				
Party	**GSK (GUK Agreement)**		**GSK (Alpharma Agreement)**	
	Adjustment	**Figure**	**Adjustment**	**Figure**
Relevant turnover	-	£67,122,000	-	£67,122,000
Step 1	21%	£14,095,620	21%	£14,095,620
Step 2	x 2.5	£35,239,050	x 1.5	£21,143,430
Step 3	-	£0	-	£0
Step 4	-40%	£14,095,620	-40%	£8,457,372
	-	£0	-55%	£11,628,887
Step 5	-	£0	-	£0
Step 6	-	£0	-	£0
Total penalty after step 6	**£21,143,430**		**£1,057,172**	
TOTAL PENALTY	**£22,200,602**			

GUK-Merck				
	GUK		**Merck**	
	Adjustment	**Figure**	**Adjustment**	**Figure**
Relevant turnover	-	£13,013,169	-	£13,013,169
Step 1	21%	£2,732,765	21%	£2,732,765
Step 2	x 2.5	£6,831,914	x 2.5	£6,831,914
Step 3	-	£0	-5%	£341,595.70
Step 4	-40%	£2,732,766	-40%	£2,596,127
	-50%	£2,049,574	-	£0
Step 5	-	£0	-	£0
Step 6	-	£0	-	£0
Total penalty after step 6	**£2,049,574 jointly and severally with Merck**		**£3,894,191 (of which, GUK is jointly and severally liable for £2,049,574)**	

Alpharma						
Party	**Actavis**		**Xellia**		**ALLC**	
	Adjustment	**Figure**	**Adjustment**	**Figure**	**Adjustment**	**Figure**
Relevant turnover	-	£5,728,620	-	£5,728,620	-	£5,728,620
Step 1	21%	£1,203,010	21%	£1,203,010	21%	£1,203,010
Step 2	x 1.5	£1,804,515	x 1.5	£1,804,515	x 1.5	£1,804,515
Step 3	-5%	£90,226	-5%	£90,226	-5%	£90,226
Step 4	-40%	£685,716	-40%	£685,716	-40%	£685,716
Step 5	-	£0	-	£0	-	£0
Step 6	-	£0	-	£0	-	£0
Total penalty after step 6	**£1,028,574** **jointly and severally with Xellia and ALLC**		**£1,028,574** **jointly and severally with Actavis and ALLC**		**£1,028,574** **jointly and severally with Actavis and Xellia**	