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IN THE COMPETITION APPEAL TRIBUNAL

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

Victoria House
Bloomsbury Place
London WC1A 2EB

8 March 2018

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

Heard at Victoria House on 27-28 February,
1-3, 6-7, 9-10, 13-16 and 27-31 March 2017

JUDGMENT

APPEARANCES

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

Mr James Flynn QC, Mr David Scannell and Ms Charlotte Thomas (instructed by Nabarro LLP) appeared on behalf of GlaxoSmithKline PLC.

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

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

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

Mr Jon Turner QC, Ms Marie Demetriou QC, Mr David Bailey, Mr Thomas Sebastian, Mr Daniel Piccinin, Mr Ravi Mehta and Ms Elizabeth Kelsey (instructed by CMA Legal) appeared on behalf of the Competition and Markets Authority.

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A. INTRODUCTION

1. By a decision dated 12 February 2016 ("the Decision"), the Competition and Markets Authority ("CMA") determined that GlaxoSmithKline plc ("GSK") had infringed both the Chapter I prohibition (concerning anti-competitive agreements) and the Chapter II prohibition (concerning abuse of a dominant position) under the Competition Act 1998 (the "CA"). Five other companies or corporate groups were also held to have infringed the Chapter I prohibition. Since one of the relevant agreements lasted beyond 1 May 2004, from which date insofar as an agreement affected trade between EU Member States the UK competition authority is required by EU Regulation 1/2003 to apply Art 101 of the Treaty on the Functioning of the European Union ("TFEU") when applying the equivalent provision of domestic law, the parties to that agreement were also found to have infringed Art 101 TFEU ("Art 101") for the brief period between 1 May 2004 and 1 July 2004 when the agreement was terminated. The CMA imposed significant financial penalties on all six companies (or the relevant companies within the corporate group).

2. The infringements arise out of three agreements (together, "the Agreements") made in 2001-02 concerning the pharmaceutical drug, paroxetine. Paroxetine is a prescription-only anti-depressant medicine that was marketed by GSK in the UK under the brand name "Seroxat". It is a so-called blockbuster drug[1], which over the relevant period was one of GSK's highest selling products, both in the UK and world-wide. At that time, paroxetine also had the sixth highest sales (by value) of any prescription drug in the UK. Each of the Agreements was made between GSK[2] and a generic supplier which had alleged that the relevant patents held by GSK over paroxetine were invalid and/or that the generic paroxetine which it intended to market in the UK did not infringe GSK's patents. Two of the Agreements were made after patent litigation between GSK and the generic supplier had commenced before the

[1] A blockbuster medicine has been defined by the European Commission as a medicine of which the annual global turnover exceeds $1 billion: Decision, fn 210.

[2] Some of the agreements were made by GSK's subsidiary, SmithKline Beecham plc. However, for convenience the companies will be referred to without distinction as "GSK" save where it is necessary to distinguish between them.

Patents Court, and involved the settlement (partial or complete) of that litigation.

3. The Agreements are as follows:

(1) An agreement between GSK and Norton Healthcare Ltd trading as IVAX Pharmaceuticals UK ("IVAX") made on 3 October 2001 and subsequently extended until finally terminated on 29 June 2004 (the "IVAX Agreement").

(2) An agreement between GSK and Generics (UK) Ltd ("GUK") made on 13 March 2002 and lasting until 1 July 2004 (the "GUK Agreement").

(3) An agreement between GSK and Alpharma Ltd ("Alpharma") made on 12 November 2002, subsequently extended and amended, and effectively terminating on 13 February 2004 (the "Alpharma Agreement").

4. It will be necessary to describe each agreement in detail below, but at the outset it should be noted that the CMA's findings of infringements by GSK concerned all three agreements, and further that:

(1) The IVAX Agreement is directly relevant only to the abuse of dominance infringement, since the CMA determined that the agreement was exempted from the Chapter I prohibition by reason of the Competition Act 1998 (Land and Vertical Agreements Exclusion) Order 2000 (the "Exclusion Order").

(2) The GUK Agreement formed the basis of the finding of infringement by GUK and also by its then parent company, Merck KGaA ("Merck").

(3) The Alpharma Agreement was the basis of the finding of infringement by Actavis UK Ltd ("Actavis"), as Alpharma became on 18 May 2006, and also by Xellia Pharmaceuticals ApS ("Xellia") and Alpharma LLC

("ALLC"), formerly respectively Alpharma ApS and Alpharma Inc, of which Alpharma was a subsidiary at the relevant time.

5. All six companies appealed against the Decision insofar as it affected them. Since the appeals by Xellia and ALLC were made jointly, there were five independent, substantive appeals. However, there is much overlap between them so they were heard together. This is a single judgment on all the appeals, although it will be necessary to deal with the particular grounds raised by each Appellant.

6. Some of the most difficult issues on the appeals concern the proper analysis and assessment under competition law of so-called 'pay-for-delay' agreements. Such an agreement involves a patent-holder paying significant sums to a generic challenger as part of an agreement in which the latter drops its patent challenge and undertakes not to seek to enter the market with an independent generic product. Since the patent-holder was usually responsible for developing and introducing the drug to the market, it is referred to as the "originator". For convenience, we shall refer to the company challenging the patent as the "generic company" or "generic supplier". Pay-for-delay agreements have been the subject of attention in recent years (largely subsequent to the Agreements on which this case focuses) by the competition authorities both in the United States and the EU, and have generated considerable academic debate.

7. Whether the Agreements here are properly to be characterised as pay-for-delay agreements is one of the matters of dispute between the parties; but even if they are, there is a question whether, in all the circumstances, they give rise to infringements of competition law. Thus the present appeals raise issues at the intersection of patent law, which in the public interest grants, subject to certain conditions, a monopoly right for a prescribed period so as to provide an incentive for innovation (and in the case of pharmaceutical drugs in particular, to incur the very substantial research and development costs involved), and competition law, which in the public interest strikes at anti-competitive arrangements and conduct which serve to exclude legitimate actual or potential competition from the market that would reduce prices.

B. THE FACTS

8. A great deal of factual material, much of it documentary, and analysis of pricing data, was presented during the course of the appeals. Rather than attempting to condense the relevant facts into one section of this judgment, we shall refer insofar as relevant to the more detailed factual matters when addressing particular issues. At the outset, we therefore describe the essential factual background to the Decision and, in more detail, the Agreements which are the fundamental basis of the findings of infringement of competition law. A schedule setting out a chronology concerning the Agreements and various patent actions is appended to this judgment.

(1) Paroxetine

9. Paroxetine belongs to the group of antidepressant medicines known as selective serotonin re-uptake inhibitors ("SSRIs"), which became available in the UK in the early 1990s. The paroxetine hydrochloride molecule (the active pharmaceutical ingredient or "API") was originally patented in 1973 and GSK acquired the rights to that patent under licensing arrangements in 1979. The protection of that patent, extended by a supplementary protection certificate, expired in January 1999 and GSK's right to data exclusivity[3] expired in December 2000.

10. By that time, GSK had obtained three additional relevant patents, two of which related to separate salt formulations of paroxetine hydrochloride and one which concerned a process for formulating tablets. These 'secondary' patents were as follows:

    (1) EP 0 223 403 (the "Hemihydrate Patent"), which covers a particular crystalline form of paroxetine hydrochloride. It was granted to GSK in 1993 and expired in October 2006.

[3] See further at para 18 below.

(2) GB 2 297 550 (the "Anhydrate Patent"), which covers four polymorphs of paroxetine hydrochloride anhydrate and the process to produce them. It was granted in 1997, and subsequently amended. As explained below, it was found to be partially invalid in proceedings before the Patents Court and, to the extent that it remained, it was due to expire in 2016.[4]

(3) EP 0 734 260 (the "Dry Tableting Patent"), which covers a process for formulating tablets containing paroxetine in the absence of water. It was granted in June 1999, but was revoked by the Opposition Division of the European Patent Office ("EPO") in May 2003. On GSK's appeal, and following the decision of the opposing suppliers to withdraw their opposition or not participate in the appeal, it was restored in 2006 and expired in 2008.

11. The particular form of paroxetine marketed by GSK is the hemihydrate salt of paroxetine hydrochloride. GSK obtained the necessary marketing authorisation for this in December 1990 and began marketing it in the UK, under the name Seroxat, in February 1991.

12. As noted above, Seroxat was a blockbuster drug. Prior to the merger with Glaxo Wellcome at the end of 2000 to form GSK, it was the biggest selling drug in the UK of SmithKline Beecham ("SB"), and in 2001-02, the period with which the Decision is principally concerned, it was the biggest selling drug in the GSK group, although not in the UK. Nonetheless, in the UK it accounted for some £71.6 million of annual sales in 2001 alone, amounting to over 10% of sales, and at the time its sales were predicted to grow. As Dr Reilly, who was finance director of GSK's UK business at the relevant time, put it, "it was a big product."

13. Over the relevant period, GSK produced Seroxat in two doses: 20mg and 30mg. The 20mg dose had both a tablet and liquid form, whereas the 30mg dose was made only as tablets. Most of the prescription of paroxetine was in

[4] In fact, the Anhydrate Patent expired in 2013 due to non-payment of renewal fees.

the community, i.e. by GPs or community psychiatrists and not in hospitals: sales to hospitals accounted for only some 2.9% of GSK's sales of Seroxat by value in 2002.[5] The 20mg dose was much the more significant: nevertheless, NHS expenditure on 30mg paroxetine accounted for about 27% of total NHS expenditure on paroxetine in 2001-02.

14. A doctor can make out a prescription either in the brand name of a drug or generically, i.e. naming the chemical compound of the drug rather than the brand. Doctors have been encouraged to write prescriptions generically, irrespective of whether a generic version of the drug is available in the market. Hence, before the launch of generic versions of paroxetine, approximately 90% of prescriptions were written generically and only 10% were written for 'Seroxat'.

15. A significant feature of the UK market for paroxetine over the relevant period, as for other leading pharmaceutical drugs, was the presence of parallel imports ("PIs"). Differences in prices for patented medicines between different EU Member States, partly reflecting the different income levels and regulatory regimes, mean that there is often a profitable parallel trade in branded prescription drugs before generic versions become available, carried on by businesses adept at taking advantage of these opportunities. The flow may vary over time depending on relative prices, which may be affected by factors such as regulatory pricing decisions and currency fluctuations, and the availability of supply. To compete with the UK branded product, the parallel importer has to charge a lower price to make the PI product attractive to pharmacies.[6] The pharmacy receives the same reimbursement sum from the NHS whether a domestically marketed product or a PI is dispensed and so a pharmacy which purchases a cheaper PI can keep the difference.[7] However, a pharmacy does not have unlimited discretion as to which product to dispense to a patient. When a prescription is made out generically, the pharmacy is free to dispense the branded product and, if available, a PI or a generic product.

[5] Decision, fn 49.
[6] They may also sell to other customers such as wholesalers, but for simplicity we refer here to their selling to pharmacists.
[7] Subject only to the operation of the 'clawback' under the NHS Drug Tariff: see paras 270-271 below.

When a prescription is made out with the brand name, the pharmacist can only dispense the branded product or a PI which is over-stickered with the brand name (if the original packaging has a different name).

16. GSK sold paroxetine, through its various European subsidiaries, in many countries in the EU under different brand names (e.g. 'Deroxat' in France). As at September 2001, PIs accounted for approximately 30-40% (by volume) of paroxetine dispensed in the UK.[8] However, PIs came only for the 20mg dosage of paroxetine; there were no PIs of the 30mg tablets. From GSK's perspective, PIs were disruptive to its business not only because they substantially reduced its profit margins but also because they made intra-group accounting more difficult. Due to limitations in the data available, not all sales of PIs in the UK were credited to GSK's UK subsidiary.

17. In response to the PI trade, GSK would offer pharmacies 'brand equalisation' deals, amounting to a discount off the list price of Seroxat if they agreed to dispense only the product which GSK supplied. We discuss brand equalisation deals in more detail below; they effectively reduced the price achieved by GSK for many of its UK Seroxat supplies close to the PI price.

18. In order to supply a pharmaceutical product on the market the manufacturer has to obtain a marketing authorisation ("MA") in the country of intended sale. Before granting a MA, the relevant authority must be satisfied as to the safety, quality and efficacy of the product in treating the conditions for which it is intended. The initial grant of a MA therefore requires the manufacturer to submit a great deal of data, including the results of clinical trials. But once a product has been granted a MA, a generic company can apply for a MA of its own version of the drug under an abridged procedure on the basis that it satisfies the test for "essential similarity": i.e. that its product is sufficiently similar both quantitatively and qualitatively to the original or 'reference' product. That avoids the need for the generic companies to carry out their own

[8] GSK's contemporaneous evidence in proceedings before the Patents Court (see para 28 below) was that PIs accounted for approximately 40% by volume of paroxetine dispensed in the UK; cf, the CMA's data relied on in the Decision, as illustrated by the Table at para 56 below, which indicates the proportion as closer to 30%.

pre-clinical and clinical trials. However, such an application for generic approval cannot be made until the expiry of a period of "data exclusivity" following the grant of the MA for the reference product. In the UK at the relevant time the data exclusivity period was 10 years (for MAs granted from November 2005 onwards the period has been reduced to 8 years). Once a MA is granted in one EU Member State, a MA can be sought in another EU Member State through the Mutual Recognition procedure (under which the application has to be determined within 90 days of receipt).

19. For GSK's Seroxat, the MA in the UK was granted on 11 December 1990. Accordingly, the data exclusivity expired on 10 December 2000. From that point on, GSK faced the possibility of generic suppliers seeking a MA under the abridged procedure to enter the UK market for paroxetine. Given the size and value of the market, this was clearly an attractive prospect for generic suppliers. As its original patent had expired in 1999 (see para 9 above), GSK could prevent such generic entry only if it could successfully rely on one or more of its secondary patents.

20. It appears that by about mid-2000, if not before, GSK was aware that a number of generic companies were actively considering entry into the UK market with generic paroxetine. In particular, GSK was aware of such a threat from IVAX, then the second largest supplier of generic medicines in the UK, and from GUK, a major generic manufacturer. By June 2000, IVAX had submitted an application for a MA in Ireland. The paroxetine API on which that application was based was obtained by IVAX from BASF AG ("BASF").[9] GUK obtained a MA for paroxetine in Denmark in April 2001. Then, on 30 May 2001, Alpharma submitted an application for a MA in the UK.

(2) The IVAX Agreement

21. Following an approach from IVAX in mid-2000, there were a series of meetings between GSK, represented by, among others, Dr Mark Reilly, and

[9] Para 3.17 of the Decision describes BASF as a major chemical company based in Germany and a leading producer of APIs for generic suppliers in 2001.

Mr David Blanksby and Mr Simon Clark of IVAX. Dr Reilly summarised the position in his witness statement as follows:

> "24. I do not recall the details of the discussions but the meetings followed a similar pattern with each party 'setting out their stall' on the patent position. IVAX were very aggressive—they said they would break our patents and launch independently and at risk. They said they had a paroxetine product. In one meeting they put a vial on the table but they would not let us take it away for testing. I recall that in at least one meeting IVAX told us they were in the process of seeking an MA for a paroxetine product in Ireland—which they eventually obtained in September 2001. We were aware that IVAX intended to use the Irish MA to seek a UK MA under the mutual recognition procedure and although the timing of this was difficult to predict, the grant of an MA gave greater credibility to their claims. They were well aware of the damage to GSK's business to which their actions would lead even if they were subsequently found to have an infringing product. We were equally clear that we would defend our patent position.
>
> 25. Of course there was the possibility that they could be injuncted from entering and we were clear that we would take legal action, but as I recall from discussions at the time, injunctions were rare in pharmaceutical cases in the UK at the time leading up to the IVAX Agreement, and GSK considered it unlikely that one could be obtained."

22. Following some 18 months of discussions, the parties entered into the IVAX Agreement, signed on 3 October 2001. Under this agreement, GSK appointed IVAX its "sole distributor" in the UK of 20 mg paroxetine hydrochloride in 30 tablet packs (the "Product"), to be sold as an authorised generic on the basis that GSK could also sell the Product, including under the Seroxat brand, but would not license or appoint any other distributors of that Product. The supply price (i.e. the price at which GSK would supply the Product to IVAX) was £8.45 per pack. The Agreement was for an initial term of 12 months commencing on 1 December 2001, subject to the right of IVAX to terminate on one month's notice, and to clause 3.2 which provided:

> "3.2 At any time during the term of this Agreement should the average price offered by any party to retail pharmacists over an average period of three (3) consecutive days for a generic product (other than Seroxat or the PRODUCT) having paroxetine hydrochloride as its active substance reach £8.45 per PACK or below IVAX shall have the option to terminate this Agreement forthwith. Written proof (such as copy invoices, trade price lists, or offers to supply) of the availability of generic product must be supplied to SB to enable termination for this event."

23. Further, the IVAX Agreement contained the following further terms:

> "5. PROMOTIONAL ALLOWANCE

> SB shall pay to IVAX a promotional allowance of £3.2 million in recognition of its promotional activities required to support the distribution and marketing of the PRODUCT. This sum shall be payable by way of monthly instalments of four hundred and fifty thousand pounds (£450,000) in the first month and thereafter eleven payments of two hundred and fifty thousand pounds (£250,000) per month to IVAX by electronic transfer to IVAX's bank account (details of which have been supplied by IVAX). In the event that this Agreement terminated before the twelve month period has expired other than by SB pursuant to clauses 3.3 or 3.4, then all outstanding instalments shall remain payable for the remaining months during that twelve month period.
>
> …
>
> 7.3 For technical reasons the quantities of the PRODUCT to be supplied to IVAX during the twelve month term of this Agreement shall not exceed seven hundred and seventy thousand (770,000) PACKS of the PRODUCT unless otherwise agreed."

24. On the same date as the IVAX Agreement and in consideration thereof, GSK and IVAX entered into a side letter agreement, concerning the infringement proceedings which GSK had just commenced against GUK. The side letter provided that in the event of GSK obtaining judgment against GUK in those proceedings, it would pay IVAX the amount of damages it recovered up to the amount of £3.2 million. And similarly, if the proceedings should settle, GSK would pay IVAX the sum received from GUK under that settlement, up to the amount of £3.2 million.

25. It appears that shortly after concluding the IVAX Agreement, IVAX appointed Tillomed Ltd to become a sub-distributor for paroxetine.

26. By a 1st Addendum, concluded on 15 February 2002, the term of the IVAX Agreement was extended by a further two years from 1 December 2002, with the supply price maintained for the first extended year and thereafter reviewed. Clauses 5 (promotional allowance) and 7.3 (volume) were replaced with equivalent provisions specifying that a "promotional allowance" of £3.2 million would be paid by GSK each year, and that the maximum volume to be supplied was (as before) 770,000 packs per year.

27. Over the period while the discussions with IVAX were taking place, litigation with other parties concerning GSK's patents started in the Patents Court. On 27 July 2001, BASF commenced revocation proceedings against certain

claims in the Anhydrate Patent. On 18 September 2001, GSK started infringement proceedings in respect of the same patent against GUK, which appeared to be about to enter the UK market. GUK counterclaimed for revocation, alleging that the patent was invalid.

(3) The GUK Proceedings and Agreements

28. GSK sought interim relief against GUK, and on 23 October 2001, Jacob J (as he then was) granted an interim injunction against GUK entering the market. In his judgment, Jacob J observed that there were serious issues to be tried as regards both infringement and validity. He held that it was "a classic *Cyanamid* case"[10], where the court could not form a view as to the relative strength of the parties' contesting arguments, but the potential effect of entry by GUK onto the market would be "to cause a [downward] price spiral." Deciding the question of interim relief on the balance of convenience where both sides' damages were unquantifiable, he held that it was a case for retention of the status quo, particularly where GUK could have had the validity of the patent resolved much earlier by putting GSK on notice so that the issue could have been determined well in advance of the date of GUK's intended launch.

29. Although, viewed with hindsight, Jacob J's decision and unreserved judgment appears to be a straightforward application of the 'balance of convenience' principles from the *Cyanamid* case, we were told that it came as something of a surprise at the time, since pharmaceutical patentees had found it difficult to persuade courts that damages would not be an adequate remedy. Perhaps the particular feature of the judgment that commanded attention was its emphasis on the importance of a challenger 'clearing the way' by taking appropriate steps well in advance, if it wished to resist interim relief.

30. The interim injunction was coupled with a direction that the case should come on for trial the following March.

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[10] i.e. governed by the principles for interim relief set out in *American Cynamid Co v Ethicon Ltd* [1975] AC 396.

31. On 30 November 2001, Jacob J refused an application by GSK to amend and have heard in the action an additional claim for alleged infringement of the Hemihydrate Patent. Shortly afterwards, on 4 December 2001, GSK commenced a separate action against GUK based on the Hemihydrate Patent. Those separate proceedings were subsequently stayed. The Court directed that the BASF case and the GUK case, which both concerned the Anhydrate Patent, should be heard together.

32. On 13 March 2002, the day before the trial was due to start, GSK and GUK reached a settlement. The injunction and cross-undertaking in damages[11] were discharged, all claims to damages were waived (including any claim by GSK under the Hemihydrate Patent), the proceedings were stayed and the parties entered into the GUK Agreement. This provided, in summary, that:

(1) GSK would purchase all GUK's stock of generic paroxetine intended for sale in the UK, for the sum of US$12.5 million.

(2) GSK would pay 50% of GUK's costs in the litigation up to £0.5 million.

(3) GUK would enter into a sub-distribution agreement with IVAX for 20mg paroxetine (the "IVAX-GUK Supply Agreement") and if that should be terminated then GSK would assume IVAX's obligations thereunder as regards delivery of paroxetine and the maintenance of a minimum level of GUK's profit.

(4) GSK would pay GUK a "marketing allowance" of £1.65 million p.a. payable in equal instalments for three years.

(5) GUK and all companies in the Merck group would not make, import or supply paroxetine hydrochloride in the UK during the currency of the

[11] i.e. the undertaking by GSK to comply with any order made by the court in the event that the court later found that the interim injunction caused loss to GUK for which GUK should be compensated.

IVAX-GUK Supply Agreement, save as purchased from IVAX or otherwise produced by GSK.

33. The GUK Agreement also provided (by clause 10) that the parties would discuss renewal of the arrangements after three years for a further three year period, and that on termination of the IVAX-GUK Supply Agreement either party would be at liberty to restore the patent litigation.

34. As reflected in clause 10, the GUK Agreement effectively had a three-year term, since that was the term of the IVAX-GUK Supply Agreement, entered into the following day, 14 March 2002. The IVAX-GUK Supply Agreement defined a "Contract Year" as 12 months from that date and each anniversary thereof. It provided that IVAX would supply GUK with 750,000 packs of 20 mg paroxetine p.a. at a price of £8.45. Further, the agreement included a profit guarantee in that if GUK's average net selling price in any Contract Year fell below £12.25 per pack, IVAX would pay it such sum as necessary to ensure that its profit that year did not fall below £2.85 million (equivalent to a margin of £3.80 per pack on 750,000 packs). In the absence of a material breach or the customary provisions concerning insolvency and receivership, etc., the only basis on which the agreement could be terminated before the end of the three-year term was pursuant to clause 4.4, which provided:

> "4.4 In the event that the Market Price per Pack[12] falls below £8.45 (exclusive of VAT) for at least three consecutive months in the third Contract Year (or any time thereafter) ("the Period") then either party may following expiration of the Period, terminate this Agreement with immediate effect on serving written notice."

35. Contemporaneously with the GUK Agreement and the IVAX-GUK Supply Agreement, on 14 March 2002, GSK and IVAX signed Heads of Agreement for amendment to the IVAX Agreement, to address the appointment of GUK as a sub-distributor. The terms of that document were then formally set out in a 2nd Addendum to the IVAX Agreement signed on 12 September 2002. It extended the term of the IVAX Agreement to 13 March 2005 (thereby

[12] Defined as the average selling price for a pack of 30 x 20mg paroxetine tablets calculated for all companies selling in the UK but excluding Seroxat sold by GSK.

aligning with the IVAX-GUK Supply Agreement). The volume supplied to IVAX was increased to 1,520,000 packs in each year commencing 14 March 2002, and this was now to be supplied in bulk form so that it could be repackaged for sale to GUK. This increased volume evidently reflected the addition to the previously agreed 770,000 packs of the 750,000 packs which IVAX was committed to supply to GUK. The 2nd Addendum further provided that in the event that GUK's average net selling price (excl VAT) fell below £12.25 per pack, GSK would pay IVAX "such sum as IVAX may be required to pay to GUK" to make up any shortfall below £2.85 million in GUK's profits on sale of paroxetine packs (defined on the basis of average net selling price less £8.45 per pack sold). GSK therefore undertook to reimburse IVAX for any liability it might have under the profit guarantee in the IVAX-GUK Supply Agreement. The supply price to IVAX was also reduced.

(4) The BASF Trial

36. The trial of the BASF action duly commenced on 14 March 2002, obviously without the participation of GUK. On 12 July 2002, Pumfrey J handed down his judgment: [2002] EWHC 1373 (Ch). He held that most of the product claims in the Anhydrate Patent were invalid, but that process claims 10(i) and 11 were valid (and that all surviving product claims must be limited to products of that process). GSK appealed against the judge's conclusion regarding one of the claims, and BASF cross-appealed. On 25 June 2003, the Court of Appeal dismissed both appeal and cross-appeal: [2003] EWCA Civ 872.

(5) The Proceedings against Alpharma and the Alpharma Agreement

37. In the meantime, shortly after the BASF trial concluded, Alpharma on 29 April 2002 obtained a MA in the UK for paroxetine. On 11 June 2002, GSK started infringement proceedings against Alpharma, relying on both the Anhydrate and Hemihydrate Patents, and sought interim relief. On 24 June 2002, Alpharma gave an undertaking to the Court not to sell paroxetine in the UK until seven days after the judgment in the BASF case, GSK gave a cross-undertaking in damages, and the Court ordered Alpharma to deliver up a

sample of its product for testing. Following the judgment in the BASF case, GSK amended its claim, relying only on the process claim in the Anhydrate Patent and dropping reliance on the Hemihydrate Patent. The matter came back for hearing before Jacob J on 1 August 2002. Both sides agreed that the trial would be short, since the only issue was whether Alpharma's product used the process described in the patent (what the judge described as "a technical question"), and that the trial could therefore come on in October. Expressly on the basis that the trial could be held quickly, Alpharma undertook not to put its product on the UK market until judgment. In fact, the trial was subsequently re-fixed for December 2002.

38. In about September/October 2002, inspection and testing took place pursuant to the Court's order. The product Alpharma intended to use was manufactured in Iceland by a company called Delta, and inspection of Delta's plant was followed by testing of a sample. The critical issue for the process claim was whether the displacement step used in the manufacturing process to remove unwanted solvent was covered by the claim. However, as explained by Ms Vivien West, a patent agent who at the time worked for GSK, the examinations were inconclusive:

> "The inspection failed to throw light on the question whether Delta was using the displacement step covered by the process claims of the Anhydrate Patent. The tests indicated that the product was an anhydrate crystallised from acetone and the level of residual acetone was lower than achievable by conventional oven drying. The known method was to use the displacement method claimed under the Anhydrate Patent."

39. Following the inspection, GSK continued to assert that Alpharma's product infringed, and it appears that both sides continued preparing for trial.

40. Meanwhile, on 30 July 2002, another generic supplier, Apotex, obtained a MA for the UK. On 9 October 2002, Apotex and its UK distributors, Neolab and Waymade, gave notice to GSK of intention to launch its product in the UK and commenced revocation proceedings as regards the Anhydrate Patent. GSK responded by starting, on 22 October, infringement proceedings against the three companies, (the "Apotex litigation").

41. Shortly afterwards, on 12 November 2002, GSK settled its action with Alpharma. Under the Alpharma Agreement, the parties agreed to an order whereby Alpharma would be discharged from its undertaking and GSK from its cross-undertaking, and GSK's claim would be dismissed. Further it was agreed that:

(1) Alpharma would enter into a sub-distribution agreement with IVAX for the supply of 500,000 packs of 20 mg paroxetine in the year commencing 1 December 2002 (the "IVAX-Alpharma Supply Agreement").

(2) GSK would pay Alpharma £0.5 million towards its legal costs in the proceedings.

(3) GSK would make a one-off payment of £3 million to Alpharma "in respect of the production and preparation costs for launch in the UK market by Alpharma of [paroxetine]".

(4) GSK would pay Alpharma a "marketing allowance" of £100,000 per month for the 12-month term.

(5) GSK would give Alpharma what was in effect an option to purchase some products which GSK was potentially divesting in three other therapeutic areas to ensure the transfer to Alpharma of value of at least £500,000 "failing which an alternative means to achieve such transfer shall be agreed" (cl.6).

(6) During the currency of the IVAX-Alpharma Supply Agreement, Alpharma would not make, import or supply paroxetine hydrochloride in the UK save as purchased from IVAX or otherwise manufactured by GSK.

42. On 20 November 2002, IVAX and Alpharma duly entered into the IVAX-Alpharma Supply Agreement. The agreement was for a one year term, commencing on 1 December 2002. IVAX agreed to supply Alpharma with

500,000 packs of 30 x 20mg paroxetine tablets in equal monthly instalments at a price of £8.45 per pack. Pursuant to clause 11.3, Alpharma could terminate the agreement on one month's notice in the event of the formation of a "Generic Market" or on the demise, "whether by invalidation, surrender, abandonment, or otherwise" of the process claim in the Anhydrate Patent. "Generic Market" was defined as follows:

> " 'Generic Market' means when a monthly average price for the Product (in thirty (30) tablets) sold by any company in the [UK] (not including [GSK] and Alpharma) falls below nine pounds and fifty pence (£9.50) per Pack or when a paroxetine 20mg product is sold other than under [GSK]'s marketing authorisation."

43. Clause 11.3 of the IVAX-Alpharma Supply Agreement further provided that for up to two months following service of such notice to terminate where the average net selling price for all companies selling in the UK (excluding GSK's Seroxat) fell below £8.45, IVAX would pay Alpharma the difference between £8.45 and that average price up to £200,000 per month (presumably calculated on the volume of stock sold by Alpharma).

44. On the same day, 20 November 2002, GSK and IVAX concluded a 3rd Addendum to the IVAX Agreement, to take account of the addition of Alpharma as a sub-distributor. The 3rd Addendum accordingly increased the volume of supply to IVAX by GSK to 2,020,000 packs per year, in bulk form. It further provided that in the event that Alpharma terminated its supply agreement from IVAX due to the market price falling below £8.45 per pack, GSK would reimburse IVAX for such sum as it had to pay Alpharma due to the price difference, up to a maximum of £200,000 per month for two months. GSK therefore undertook to reimburse IVAX for any liability it might have under cl. 11.3 of the IVAX-Alpharma Supply Agreement.

45. On 14 November 2003, GSK and Alpharma agreed to amend the Alpharma Agreement, extending it by a further year, to expire on 30 November 2004. The Amendment provided that:

(1) The supply to Alpharma would be for 620,000 packs of 30 x 20mg paroxetine in consideration for extinguishing the obligation to transfer value of £500,000 under cl. 6 of the Alpharma Agreement.

(2) GSK would pay Alpharma a "marketing allowance" of £100,000 per month.

46. GSK does not appear to have agreed a further Addendum[13] to the IVAX Agreement to reflect this increased volume, but that was probably because the Amendment to the Alpharma Agreement was rapidly overtaken by events, following judgment in the Apotex litigation.

(6) The Apotex Judgments

47. On 28 November 2002, Jacob J had granted an interim injunction restraining Apotex, Neolab and Waymade from selling its paroxetine on the UK market, broadly following the approach he had taken in granting GSK an injunction against GUK: [2002] EWHC 2556 (Pat). An appeal against that decision was dismissed on 14 February 2003: [2003] EWCA Civ 137.

48. On 25 June 2003, the trial commenced before Pumfrey J. In his judgment, delivered on 5 December, the judge held that the remaining claims (i.e. those which had not been invalidated in the BASF judgment: para 36 above) were invalid and that, in any event, on its true construction the process claim was plainly not infringed by the process used by Apotex: [2003] EWHC 2939 (Ch). Although GSK obtained permission to appeal, it did not seek to renew the injunction pending appeal, and on 18 December 2003 the interim injunction was accordingly discharged.[14]

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[13] There had in the meantime been a 4th Addendum to the IVAX Agreement, agreed on 28 February 2003, but that is only relevant to the present appeals in that the "promotional allowance" payable to IVAX was increased to £3.45 million for the second contract year and to £3.5 million for the third contract year.

[14] On 29 November 2004, the Court of Appeal reversed the judge's finding of invalidity, but upheld his conclusion that there was no infringement: [2004] EWCA Civ 1568.

49. Although the Apotex product was found not to infringe the Anhydrate Patent, this does not necessarily mean that the GUK or Alpharma products would similarly have been found not to infringe since this was a process patent and those products may have been made by a different procedure.

(7) Independent generic entry and the effect on price

50. Following Pumfrey J's judgment in the Apotex case and GSK's decision not to seek a further injunction, Neolab and Waymade entered the market in late December 2003 as distributors for Apotex. The market was now effectively open.

51. On 13 January 2004, Alpharma gave IVAX one month's notice to terminate the IVAX-Alpharma Supply Agreement pursuant to clause 11.3; para 42 above. That had the effect of similarly ending the restriction on Alpharma under the Alpharma Agreement: para 41(6) above. In February 2004, Alpharma entered the market with its own, independently sourced paroxetine.

52. GUK did not terminate the IVAX-GUK Supply Agreement until 25 June 2004. Pursuant to clause 4.4, it could not do so until the market price had fallen below £8.45 per pack for three consecutive months in the year commenced 14 March 2004, which effectively prevented it from terminating before 14 June 2004 at the earliest: para 34 above. Termination of the IVAX-GUK Supply Agreement had the effect of ending the restriction in the GUK Agreement on the sale of independent product by GUK. The GUK Agreement itself was in any event terminated by agreement between GSK and GUK on 1 July 2004.

53. Four days after the termination of the IVAX-GUK Supply Agreement, on 29 June 2004, IVAX and GSK terminated the IVAX Agreement with immediate effect. As provided for in that agreement, GSK paid IVAX £2.362 million, being the sum of the monthly instalments of the "promotional allowance" that would have been paid over the remainder of the contract year.

54. None of the agreements discussed above involved supply of the more expensive, but less frequently prescribed, 30mg paroxetine. The first independent generic entry (i.e. with independently sourced product, not supplied by GSK) by Neolab and Waymade was with a 20mg product, but in February 2004 Alpharma entered with a 30mg product, followed by a 20mg product shortly afterwards. Although there was much controversy about aspects of pricing in the course of these appeals, it is not in dispute, and is indeed unsurprising, that the effect on prices of independent generic entry was dramatic. The Decision records that for 20mg paroxetine, in the first three months following generic entry in December 2003, prices fell by 34%; and that they had fallen by 69% one year later (representing a fall from £12.95 to £3.97 per pack over the year).[15] For 30mg paroxetine, the price had fallen by around 66% by December 2005.[16] Average paroxetine prices (for both 20mg and 30mg) had fallen by around 74% by December 2005.[17]

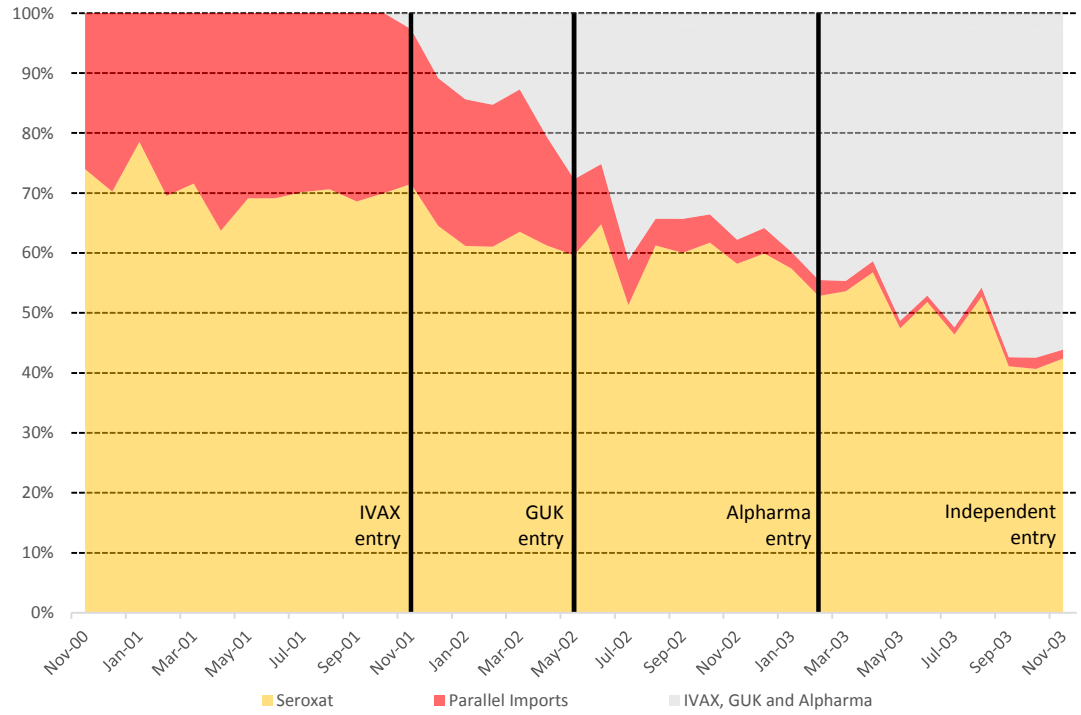
55. In summary, the Agreements between GSK and the generic companies IVAX, GUK, and Alpharma avoided (in the case of IVAX) or ended patent litigation between them, provided the generic companies with significant but limited volumes of paroxetine manufactured by GSK which they could sell under their own brand names at prices expected to be highly profitable for them, and also gave them various other payments which further increased the profitability of the Agreements. The IVAX and Alpharma Agreements could be terminated if or when generic supplies of paroxetine from other companies entered the UK market and the GUK Agreement could be terminated following such a development after three months in the third year of the Agreement.

56. The impact of the Agreements on the relative volumes of paroxetine in the UK market (i.e. Seroxat, PIs and generic supply) is illustrated by a graph derived

[15] Decision, para 3.387.
[16] Decision, para 3.388.
[17] Decision, para 3.390.

from the expert evidence submitted by GUK in the proceedings, that reflects data gathered by the CMA:[18]

Paroxetine 20mg tablets monthly volume market share: November 2000 to November 2003



C. THE DECISION

57. The background to the investigation into the Agreements was the Report on the competition inquiry into the pharmaceutical sector, conducted by the European Commission ("the Commission") pursuant to Art 17 of Regulation 1/2003 and published in July 2009. This found that among settlement agreements concluded between originator and generic companies a significant proportion had included a restriction on the generic company's ability to market its product and a value transfer from the originator to the generic company. The Commission's report concluded that such agreements were potentially anticompetitive, "in particular where the motive of the agreement is

[18] Fig 1 to Dr Majumdar's Report shows separately a very small volume of additional PI supply from about July 2002 onwards to Tillomed, Waymade and Sandoz, which is obscured in the graph, but the proportion is so small that it does not materially affect the representation shown.

the sharing of profits via payments from originator to generic companies to the detriment of patients and public health budgets" (p. 19). However, any enforcement action would have to be undertaken on a case-by-case basis, having regard to the detailed specifics of each case and the legitimate objectives of the patent regime.

58. The Commission then drew the attention of the Agreements to the Office of Fair Trading ("OFT"), the predecessor of the CMA, and provided it with copies of the Agreements in July 2010. After a preliminary investigation, the OFT opened a formal investigation under sect 25 CA on 11 August 2011. The OFT finally issued a statement of objections on 19 April 2013. Following further information gathering by the OFT and then the CMA, and extensive representations from the various parties, the CMA concluded that there were no grounds for action regarding the IVAX Agreement, and adopted the Decision on 12 February 2016.

59. The Decision is a very substantial document. It runs to 708 pages, including 477 pages of substantive text followed by 16 Annexes. The main text is divided into 11 sections, including sections addressing market definition and dominance, an object assessment, an effects assessment, assessment of abuse of a dominant position, and the attribution of liability.

60. The final section of the Decision deals with the CMA's enforcement action. The CMA determined that the addressees of the Decision should pay financial penalties for the particular infringement for which they were found liable. The CMA imposed penalties totalling £44,990,421 on the addressees. GSK received the largest penalty, being fined £37,606,275 for its infringement of the Chapter II prohibition. The CMA also calculated fines to impose on GSK in respect of the infringements of the Chapter I prohibition and Article 101. However, as explained at para 11.62 of the Decision, the CMA reduced these fines to zero since they related to materially the same facts and time periods as the Chapter II infringement and did not exceed the fine imposed in respect of the Chapter II infringement. The penalties that would have been imposed on GSK, and the penalties actually imposed on the other addressees (including

their respective joint and several liability), are summarised in the two tables below.

Infringement: GUK-GSK Agreement	
Fine imposed on GSK:	**£0** (reduced from £31,715,145)
Total fine imposed on GUK-Merck:	**£5,841,286**
- joint and several liability of Merck:	Entire sum (£5,841,286)
- joint and several liability of GUK:	£2,732,765

Infringement: Alpharma-GSK Agreement	
Fine imposed on GSK:	**£0** (reduced from £1,057,172)
Total fine imposed on Alpharma:	**£1,542,860**
- joint and several liability of Actavis:	Entire sum (£1,542,860)
- joint and several liability of Xellia:	Entire sum (£1,542,860)
- joint and several liability of ALLC:	Entire sum (£1,542,860)

D. THE APPEALS

61. As mentioned above, all the appeals were heard together. However, since the finding of an abuse of a dominant position contrary to the Chapter II prohibition was made only as regards GSK, that aspect was considered in a discrete part of the hearing which the representatives of the other Appellants did not attend.

62. As regards the Chapter I prohibition, there was substantial overlap between the grounds of appeal put forward by the various Appellants and the general issues raised. Each Appellant challenged both the finding of infringement and, in any event, the penalty imposed. Through cooperation between the Appellants' representatives, significant duplication in the written and oral submissions was avoided. We are grateful to all the Appellants' representatives for the efficient conduct of the hearing. The hearing was also greatly facilitated by electronic document management, which meant that the relevant document could rapidly

be displayed on screen without the need to search in one of the numerous trial bundles.

63. These appeals were somewhat unusual in that the greater part of the evidence at the hearing was devoted to expert economic evidence. However, GSK adduced evidence from six witnesses of fact and the CMA put in evidence from one factual witness.[19] Three of the GSK witnesses were cross-examined: Dr Mark Reilly, Ms Vivien West and Mr Andrew Sellick:

Dr Reilly

64. Dr Reilly had left the employment of GSK at the end of 2014, after holding a number of management roles in the group. He is a qualified chartered accountant and also has a degree in medical science and a PhD in pharmacology. From October 1999 to June 2003, and thus over most of the period with which the Decision is concerned, he was the Finance Director of GSK's UK pharmaceutical business, and effectively part of the management team running that business. Dr Reilly gave evidence in all the interim applications in the actions concerning the Anhydrate Patent – against GUK, against Alpharma and against Apotex. It is now many years since the events giving rise to the Decision, but before attending the hearing in the Tribunal Dr Reilly had spent time familiarising himself with many of the contemporary documents provided to him by GSK's solicitors.

65. Dr Reilly clearly had a close involvement in, and considerable knowledge of, the material events. He was cross-examined by Mr Turner QC for the CMA for 1½ days. We consider that he was an honest witness but, as GSK's Counsel themselves acknowledged in their closing submissions, he was "rather combative and defensive". We found him reluctant to accept even obvious points when he felt they might potentially prejudice GSK's case. Save where his evidence was unchallenged or manifestly correct, we therefore

[19] There was also a brief witness statement from a solicitor to Xellia and ALLC concerning the provision of certain documents.

prefer to base our findings on the contemporary documents directly rather than on the interpretation which Dr Reilly gave to them many years later.

Ms West

66. Ms West is a chartered patent agent and European Patent Attorney. She very recently retired, having previously been employed by GSK and its predecessor companies since 1986. She showed a deep familiarity with the issues involved in the various litigation over the paroxetine patents. She was a clear and frank witness who gave direct answers to the questions she was asked.

Mr Sellick

67. Mr Sellick has worked for GSK and before it for SB for more than 20 years. From January 2001 to early 2003, he was a regional sales manager for GSK's Eastern region, which covered London, East Anglia and South-East England. In that capacity, he managed a team of 12 account managers who dealt with pharmacies. Mr Sellick's evidence concerned the marketing and sales of Seroxat. We found his evidence very helpful in explaining some of the contemporary data, and also the practicalities of distribution and competition from PIs. Indeed, his evidence was not really challenged.

68. The three other witnesses adduced by GSK were:

(1) Ms Sylvia Nicholson, who is now policy director for a subsidiary of GSK but from December 2002 to February 2004 was Seroxat marketing manager at GSK. Her testimony, given from a marketing perspective, concerned the drugs which were regarded as competing with Seroxat and, in consequence, the way Seroxat and those competitors were marketed.

(2) Mr Charles Horridge, who was until 1 October 2004 the Finance Executive for the Pharmeceutical Services Negotiating Committee, a body that represents the interests of community pharmacies in the UK. His evidence concerned the NHS Drug Tariff and the operation of

"Discount Inquiries" that were instigated to quantify the level of discount earned by community pharmacies off NHS Drug Tariff prices.

(3) Mr Richard Heath, who gave brief testimony regarding the change, following the merger of SB with Glaxo Wellcome, in the distribution system used for the former SB products (such as paroxetine) from the use of independent wholesalers to a direct-to-pharmacy model, whereby GSK itself sold the drugs to the pharmacies.

Since none of this evidence was challenged it of course stands to be accepted in full.

69. The CMA put in a witness statement from Mr Andrew Collier, who since November 2006 has been the Managing Director of Newbridge Pharma Ltd, a pharmaceutical company based in Devon. Between 1997 and May 2003, and thus over the period to which the Decision relates, Mr Collier had been Director of Sales and Marketing at Alpharma. Mr Collier had overall responsibility for setting prices for Alpharma's paroxetine product. His testimony in this appeal concerned Alpharma's customers and distribution scheme at the material time, and the pricing arrangements agreed with wholesalers by Alpharma and its competitors. We note that Mr Collier made a number of witness statements in the GSK-Alpharma litigation and was also involved 'behind the scenes' assisting those at Alpharma negotiating the Alpharma Agreement with GSK. Mr Collier also signed the Alpharma Agreement on behalf of Alpharma, although he did not participate in the settlement negotiations himself. However, these matters were not discussed in his statement for these appeal proceedings. None of the Appellants sought to challenge his evidence.

70. Apart from GSK, none of the other Appellants put forward any factual witness evidence. We found it unfortunate that there was no direct evidence before the Tribunal from any individual in any of those companies involved in either the negotiation of the relevant Agreement or the selling of generic paroxetine which resulted, particularly when a relevant witness could be readily identified on the basis of the contemporary documents and statements given to the

OFT/CMA in the course of the investigation. Mr Kon, appearing for GUK, urged that there was no particular need to call such witnesses, and in particular Mr Mike Urwin, who it is accepted was the key decision-maker in the GSK-GUK litigation and as regards the GUK Agreement, since they had given sworn witness statements to the CMA in the course of its investigation, accompanied by a statement of truth, and had been interviewed by the CMA, for which a criminal penalty applied if what was said was false or misleading. He submitted that such statements and interviews should therefore be given equal weight to evidence given in this appeal.

71. We do not accept that submission. The prior witness statements and interview transcripts are of course admissible, but they are not testimony before the Tribunal and that evidence cannot be tested by cross-examination on behalf of the CMA or indeed explored by questions from the Tribunal. Nor is it simply a question of the honesty of a witness: evidence can be unreliable through poor recollection, or because a witness has genuinely persuaded himself of what happened many years before, without any element of recklessness. The offence under sect 44 CA to which Mr Kon referred applies only if a person either knows or is reckless as to whether the information supplied to the CMA is false or misleading.

72. The CMA submitted that we should draw an adverse inference from GUK's and Alpharma's failure to call relevant witnesses, such as Mr Urwin (from GUK) and, in particular, Mr Jakob Poulsen and Mr Torben Laursen (from Alpharma). However, we do not think this is a case for any adverse inference, since this is not a situation of complete silence. But we consider that insofar as such prior statements cover matters that are in issue, relatively little weight can be placed on either a witness statement or answers in interview with the investigating authority, which inevitably tend to be self-serving, by an individual who is not called to give direct evidence to the Tribunal, particularly when there is no good reason why he or she could not have been called. Mr Kon offered no reason why Mr Urwin would not have been available to give evidence. Ms Ford, appearing for Actavis, stressed that the relevant business was no longer owned by her client. But she did not suggest that Actavis or its solicitors were unable to contact the individuals in question

or that they would have been unwilling to testify. However, unlike Mr Kon, Ms Ford did not seek to rely on statements made in the course of the investigations leading up to the Decision but instead placed reliance on the contemporaneous documents.

Expert Evidence

73. The Tribunal received extensive expert evidence from no less than five economists, although the testimony from some of the experts was confined to certain issues. As a result, there were two separate joint statements of issues from the economic experts: the first from Dr Jenkins, Dr Majumdar, Prof Shapiro and Dr Stillman; and the second from Dr Majumdar, Dr Stillman and Ms Rachel Webster. Moreover, not all four experts involved in the first statement addressed all the issues. We found those statements extremely useful, although the second, for complex reasons, was rather lengthy. We heard the oral evidence from the experts in three stages: the evidence covered by the first joint statement going to the Chapter I prohibition, which was of a more conceptual nature, was heard concurrently, in a so-called 'hot tub'. Having four experts present their evidence that way was challenging for them, but they handled it very professionally and in a non-confrontational manner which was very effective. The balance of the first statement went to the Chapter II prohibition: that was addressed only by Dr Stillman and Prof Shapiro, and their oral evidence on those issues was also heard concurrently in a separate session. For both those sessions, following questioning by the Tribunal, Counsel to the relevant parties were given the opportunity to ask supplementary questions by cross-examination. The issues covered by the second joint statement were of a much more detailed nature and the oral evidence as to that was given in the traditional manner.

74. We comment briefly on the five economists:

- Dr Robert Stillman (called by GSK) presented testimony covering all the economic issues. He gave thorough and thoughtful oral evidence, following his very clear, if somewhat over-long, written reports.

- Prof Carl Shapiro (called by the CMA) was similarly impressive and very thoughtful. He has published some of the leading academic articles on pay-for-delay issues in the US, but he focused his opinions here on the specific facts of the present case. GSK submitted that Prof Shapiro tended to adopt an adversarial style and engage in advocacy, by contrast with Dr Stillman. That is not our view: on the contrary, we found that both Prof Shapiro and Dr Stillman sought to respond constructively to the points made by the other and find common ground where possible.

- Dr Adrian Majumdar (called by GUK) and Dr Helen Jenkins (called by Merck) are both very experienced at giving expert evidence in competition cases and are of undoubted technical competence. Although their written evidence was helpful, we found that in response to questioning each was reluctant when addressing conceptual matters to concede that there might be any other perspective that might apply beyond the opinion that they were putting forward.

- Ms Rachel Webster (called by the CMA) had come into the case at relatively short notice, after an initial report had been served by another economist who had to withdraw for personal reasons. She responded to detailed cross-examination with direct and clear answers and showed a mastery of the data which she had considered and analysed. Although GSK sought strongly to criticise her for steadfastly defending the position she had adopted, we do not regard that as a recrimination if she had good reasons to support her views: as to that, we found that she put forward persuasive grounds for her opinions when challenged, and was in fact prepared to contemplate and accept qualifications or corrections when she felt that they were soundly based. She was an impressive witness.

75. In addition, the Tribunal had an expert's report from Prof Allan Young, put forward by GSK. Prof Young is Professor of Psychiatry and Chair of Mood Disorders and Director of the Centre for Affective Disorders at the Institute of Psychiatry, Psychology and Neuroscience at King's College, London. His report addressed in particular the range and nature of antidepressants available in 1998-2003 to treat various conditions and the extent of clinical

substitutability between paroxetine and other similar drugs. Prof Young's evidence was not challenged.

76. As mentioned above, a large number of contemporary documents were produced in the course of the investigation by the OFT and CMA, and further considered for these appeals. However, it is clear that the very significant passage of time between the material events and the investigation leading to the Decision has impeded the assembly and therefore full and accurate assessment of data, regarding such matters as pricing, discounts and volumes of supplies. That understandably caused difficulties for the parties, and in particular for the economic experts, which were regrettable.

E. THE LAW – GENERAL

77. As stated above, all of the Appellants were found to have infringed the Chapter I prohibition, and GSK and GUK were found also to have infringed Art 101 by reason of the GUK Agreement lasting beyond 1 May 2004, when EU Regulation 1/2003 entered into force. However, that infringement of Art 101 is of only peripheral relevance since it effectively overlaps with the Chapter I prohibition, save only as regards potential exemption under the Exclusion Order which applies only to the Chapter I prohibition.

78. The Chapter I prohibition is prescribed by sect 2 CA, which states, insofar as material:

> "**2 Agreements etc. preventing, restricting or distorting competition**
>
> (1) Subject to section 3, agreements between undertakings, decisions by associations of undertakings or concerted practices which—
>
> (a) may affect trade within the United Kingdom, and
>
> (b) have as their object or effect the prevention, restriction or distortion of competition within the United Kingdom,
>
> are prohibited unless they are exempt in accordance with the provisions of this Part.
>
> (2) Subsection (1) applies, in particular, to agreements, decisions or practices which—
>
> …

(b) limit or control production, markets, technical development or investment;

(c) share markets or sources of supply"

79. Sect 9 CA provides as follows:

> **"9 Exempt Agreements**
>
> (1) An agreement is exempt from the Chapter I prohibition if it –
>
> (a) contributes to –
>
> (i) improving production or distribution, or
>
> (ii) promoting technical or economic progress,
>
> while allowing consumers a fair share of the resulting benefit; and
>
> (b) does not –
>
> (i) impose on the undertakings concerned restrictions which are not indispensable to the attainment of those objectives; or
>
> (ii) afford the undertakings concerned the possibility of eliminating competition in respect of a substantial part of the products in question.
>
> (2) In any proceedings in which it is alleged that the Chapter I prohibition is being or has been infringed by an agreement, any undertaking or association of undertakings claiming the benefit of subsection (1) shall bear the burden of proving that the conditions of that subsection are satisfied."

80. Further, sect 10 CA provides for "parallel exemptions" whereby, if an agreement is exempt from Art 101 by reason of a EU block exemption regulation (or would be if it affected trade between EU Member States), it will similarly be exempt from the Chapter I prohibition. In this case, GSK contends that the Agreements fell within Regulation (EC) No 2790/1999 (the "Vertical Block Exemption Regulation" or "VBER"). We will consider the relevant terms of the VBER when we address this ground of appeal.

81. The Chapter II prohibition is prescribed by sect 18 CA, which states, insofar as material:

> "**18 Abuse of dominant position**
>
> (1) …, any conduct on the part of one or more undertakings which amounts to the abuse of a dominant position in a market is prohibited if it may affect trade within the United Kingdom.

(2) Conduct may, in particular, constitute such an abuse if it consists in—

…

(b) limiting production, markets or technical development to the prejudice of consumers;…"

82. Sect 50 CA enables the Secretary of State to make an order providing for any provision in Part I of the Act (which encompasses sects 2 and 18) not to apply to vertical agreements or land agreements, as defined in the order, and further to provide that such an exclusion is not to apply in prescribed circumstances. The Exclusion Order, which came into effect on 1 March 2000, was made pursuant to that power and excluded "vertical agreements" from the Chapter I prohibition. It was revoked with effect from 30 April 2005, but that does not affect its potential application in the present case. We will consider the terms of the Exclusion Order when addressing this aspect of the appeals. The Exclusion Order did not provide any exclusion from the Chapter II prohibition and of course did not affect the application of Art 101 TFEU.

83. The Chapter I and Chapter II prohibitions are substantively the same as, respectively, Art 101 and Art 102 TFEU ("Art 102"), save that they require an effect on trade in the UK as opposed to an effect on trade between EU Member States, and the conditions for individual exemption under sect 9 CA mirror those in Art 101(3). The decisions of the Commission and judgments of the EU Courts – the Court of Justice of the European Union ("CJEU") and the General Court – are therefore of direct relevance to the application of the domestic provisions. In that regard, sect 60 CA provides:

"**60 Principles to be applied in determining questions**

(1) The purpose of this section is to ensure that so far as is possible (having regard to any relevant differences between the provisions concerned), questions arising under this Part in relation to competition within the United Kingdom are dealt with in a manner which is consistent with the treatment of corresponding questions arising in EU law in relation to competition within the European Union.

(2) At any time when the court determines a question arising under this Part, it must act (so far as is compatible with the provisions of this Part and whether or not it would otherwise be required to do so) with a view to securing that there is no inconsistency between—

(a) the principles applied, and decision reached, by the court in determining that question; and

(b) the principles laid down by the Treaty and the European Court, and any relevant decision of that Court, as applicable at that time in determining any corresponding question arising in EU law.

(3) The court must, in addition, have regard to any relevant decision or statement of the Commission."

84. Accordingly, it is common ground that the Chapter I and Chapter II prohibitions are to be interpreted and applied in the same way as, respectively, Art 101 and Art 102. The analysis of the law in this judgment is therefore based largely on the jurisprudence under EU competition law.

85. On 8 September 2016, the General Court handed down its judgments dismissing six appeals against the decision of the Commission of 19 June 2013 in Case AT.39226 – *Lundbeck*, which had found that all the appellants had infringed Art 101 by reason of agreements settling or pre-empting patent disputes. There were accordingly six judgments, as follows: Case T-472/13 *Lundbeck* EU:T:2016:449; Case T-467/13 *Arrow* EU:T:2016:450; Case T-469/13 *Generics (UK)* EU:T:2016:454; Case T-470/13 *Merck* EU:T:2016:452; Case T-460/13 *Sun and Ranbaxy* EU:T:2016:453; and Case T-471/13 *Xellia and Alpharma* EU:T:2016:460. Unsurprisingly, there is substantial overlap between the terms of those judgments (together, the "*Lundbeck* judgments") but there are some distinct points addressed in the individual judgments. The CMA strongly contended that the *Lundbeck* judgments support some of the key aspects of the Decision, in particular as regards the finding of infringement of Chapter I by object. The Appellants all submitted that the *Lundbeck* judgments were distinguishable, and that in fact those judgments gave support to the appeals here. However, the *Lundbeck* judgments are themselves under appeal to the CJEU.[20]

86. Further, on 9 July 2014, the Commission adopted its decision in Case AT.39612 – *Perindopril (Servier)*, finding that Servier and various generic

[20] Cases C-591/16 P *Lundbeck*; C-601/16 P *Arrow*; C-568/16 P *Sun and Ranbaxy*; C-588/16P *GUK*; C-614/16P *Merck*; *GUK*; and C-611/16P *Xellia and Alpharma*.

companies had infringed Art 101 by reason of a number of patent settlements, and that Servier had also thereby infringed Art 102. It was accepted that the *Servier* decision was relevant to the present case, in particular as regards a 'by object' infringement of the Chapter I prohibition and market definition for the purpose of the Chapter II prohibition, but GSK urged that we should not follow it, pointing out that under sect 60(3) CA we were not bound to do so. However, there have been a series of appeals by the addressees of the *Servier* decision, including Servier itself: Case T-691/14 *Servier*; Case T-677/14 *Biogaran*; Case T-680/14 *Lupin*; Case T-679/14 *Teva*; and Case T-705/14 *Unichem Laboratories*. Oral argument in those appeals was heard by the General Court in June-July and October 2017, and judgments are pending. It seems very possible that there will then be further appeals to the CJEU.

87. In the light of this, the question arose whether the Tribunal should make a reference to the CJEU for a preliminary ruling pursuant to Art 267 TFEU. We consider that on a number of issues there is a potentially close similarity with the present appeals and the *Lundbeck* and *Servier* cases. Rather than postponing for further argument, possibly at appellate level, whether any principles enunciated in those cases are directly applicable or distinguishable, and if distinguishable what the applicable principles might be in the light of those eventual judgments, we consider it is appropriate for this Tribunal now to refer the relevant questions of the interpretation of EU law arising on the present appeals which may be affected by the *Lundbeck* and *Servier* cases. Having regard to para 23 of the CJEU's Information Note on references form national courts for a preliminary ruling (OJ 2009 C 297), where we have ourselves reached a provisional view on what we consider the answer should be, we shall set that out in this judgment, as that might be of assistance to the CJEU.

88. In any event, in this judgment we shall deal with all questions of fact and, moreover, decide those issues on which either no question of the interpretation of EU law arises or on which we consider it is unnecessary to seek a ruling from the CJEU.

F. THE CHAPTER I PROHIBITION (AND ART 101 TFEU)

89. The key issues raised in the various appeals that relate to the Chapter 1 prohibition (and Art 101 TFEU) were:

(1) Were GUK and Alpharma potential competitors of GSK in the supply of paroxetine in the UK?

(2) Did the GUK Agreement and/or the Alpharma Agreement have the object of restricting competition?

(3) Did the GUK Agreement and/or the Alpharma Agreement have the effect of restricting competition?

(4) Does either the GUK or Alpharma Agreement fall within the exclusion provided under the Exclusion Order?[21]

(5) (On GSK's appeal only), do the GUK and Alpharma Agreements satisfy the conditions of the VBER or alternatively of individual exemption under sect 9 CA?

We address these issues in turn.

(1) Were GUK and Alpharma potential competitors of GSK in the supply of paroxetine in the UK?

90. The CMA found that GUK and Alpharma were potential competitors of GSK, which was treated as a condition for concluding that the respective Agreements had the object of restricting such competition. This finding of potential competition was challenged by the Appellants: it is part of Ground 3 of GSK's appeal; Ground 1 of GUK's appeal; part of Ground 1 of Merck's appeal; part of Ground 1 of Actavis' appeal; and raised inferentially although not directly under Ground 1 of Xellia/ALLC's appeal.

[21] This issue was not raised on Merck's appeal.

91. It is well established that Art 101 applies to an agreement restricting potential competition as well as actual competition. Hence in Case T-519/09 *Toshiba v Commission* EU:T:2014:263,[22] the General Court dismissed an appeal against the Commission's decision holding that a "Gentlemen's Agreement" between European and Japanese producers of power transformers not to sell in each others' home markets was a restriction of competition by object. The Court rejected the argument that the agreement could not restrict competition because the Japanese producers were not competitors on the European market, stating, at para 230:

> "… Article 81 EC protects not only actual competition, but also potential competition between undertakings. Consequently, an agreement such as the Gentleman's Agreement, which is designed to protect the European producers in their home territories from actual or potential competition from Japanese producers, is capable of restricting competition, unless insurmountable barriers to entry to the European market exist which rule out any potential competition from Japanese producers. In the present case, the Commission could therefore restrict itself to showing that the barriers to entry to the European market were not insurmountable."

92. The test for potential competition is whether, in the light of the structure of the market and the relevant context, there are real, concrete possibilities for an undertaking to enter the market in question and compete with established undertakings: Case T-461/07 *Visa Europe and Visa International v Commission* EU:T:2011:181, para 166. There, the Commission had found that the decision of the institutions in the Visa payment card network to refuse to admit the US bank, Morgan Stanley, to membership in the EU region violated Art 101. In annulment proceedings before the General Court, Visa contended that the Commission had failed to establish that Morgan Stanley was a potential competitor. The General Court, enunciating the test set out above, accepted that demonstration of the possibility of entry must be based on more than a mere hypothesis. It stated, at para 168:

> "It necessarily follows that, while the intention of an undertaking to enter a market may be of relevance in order to determine whether it can be considered to be a potential competitor in that market, nonetheless the essential factor on which such a description must be based is whether it has the ability to enter that market."

[22] Appeal dismissed: Case C-373/14P *Toshiba v Commission* EU:C:2016:26.

93. The General Court then (at para 171) approved the approach in the Commission's Guidelines on horizontal cooperation agreements, as follows:

> "It is stated in footnote No 9 in the Guidelines on cooperation agreements that '[a] firm is treated as a potential competitor if there is evidence that, absent the agreement, this firm could and would be likely to undertake the necessary additional investments or other necessary switching costs so that it could enter the relevant market in response to a small and permanent increase in relative prices.' Moreover, '[t]his assessment has to be based on realistic grounds, the mere theoretical possibility to enter a market is not sufficient.' It is also stated the '[m]arket entry needs to take place sufficiently fast so that the threat of potential entry is a constraint in the market participants behaviour' and that, '[n]ormally, this means that entry has to occur within a short period.' In that regard, the Commission refers to a period of one year while stating that 'in individual cases longer time periods can be taken into account' and the '[t]he time period needed by companies already active in the market to adjust their capacities can be used as a yardstick to determine this period.'"

94. Applying that approach, the General Court emphasised that the ability of Morgan Stanley to enter the market was not in question, and noted that it had experience of equivalent markets outside the EU and that there was some evidence of its intention. It concluded that: "the possibility of Morgan Stanley entering the market in question was not purely theoretical but, on the contrary, represented a plausible assumption." Accordingly, Morgan Stanley was a potential competitor: paras 186-187.

95. Turning to the application of these principles to the facts here, it is necessary to consider separately the position of GUK and Alpharma.

(a) GUK

96. GUK does not challenge the findings in the Decision that it had both the ability and firm intention to enter the market, and indeed that it would have done so if GSK had not obtained the interim injunction against it. In particular, it is clear from the witness statement of Mr Richard Saynor, the Sales & Marketing Director of GUK, of 15 October 2001 in the Patents Court, opposing an interim injunction, that:

(1) GUK plans on a long term basis and had been working on its paroxetine project since about 1997;

(2) Considerable sums had been invested in product development and launch:

> "14. […] To date, the Merck Group has spent almost $8 million on raw material for development and product launch; of this sum, over $6 million has been invested in the UK exercise alone, a cost which GUK has borne. A great deal of time, money and effort has been invested in developing a stable product, researching quality raw material suppliers and planning to bring the product to market, including most importantly the obtaining of regulatory approval. The cost of the initial raw material acquired for testing purposes alone exceeded $300,000. We have since acquired a further $7.5 million worth of raw material, of which $3 million worth is destined solely for the UK launch. A further $3 million worth has been earmarked to supply the UK market in the first year, although it is impossible to say with accuracy whether this amount will be sufficient. Due to the length of the synthetic process for the production of the raw material, orders must be placed six months in advance, and therefore our supplier is currently seeking confirmation of our requirements for supply in the first quarter of 2002."

(3) GUK had been actively seeking customers before the grant of the injunction, and indeed there were customers who had stopped stocking PI product in the expectation of taking supplies from GUK. Before the commencement of those proceedings, GUK had taken orders for almost half a million packs of paroxetine, amounting to about £5.5 million sales for October 2001:

> "47. …many of our customers will not have built up stocks of Seroxat from parallel importers in recent months in the expectation that GUK will launch its paroxetine product."

(4) GUK was keen to be the first to bring a generic product to the UK market. It was jealous of its reputation (or so it believed) of being one of the most innovative generic companies. And as Dr Reilly said in his evidence:

> "All of the generic companies wanted to be on the market first. It gave them kudos within the market, it was a source of competition between them."

97. Further, GUK had acquired significant stocks of generic paroxetine in preparation for launch of its product. Indeed, it was a term of the GUK Agreement that those stocks would be purchased by GSK. Accordingly, Mr Saynor wrote to Dr Reilly on 26 March 2002:

> "We … confirm that the quantity of product designated for the UK amounts to 474.75kg. This quantity is made up of active raw material, bulk product, finished product, samples taken and product lost in manufacture."

98. Although it is therefore clear – and indeed was not disputed - that GUK would have entered 'at risk' if not restrained, it was submitted that the grant of the interim injunction on 23 October 2001, and then the commencement by GSK of separate proceedings for infringement of the Hemihydrate Patent, led GUK to doubt the strength of its patent arguments and thus to increasing concern about its exposure. Thus Mr Kon, for GUK, stated in his opening submissions that it was not the value transfer (i.e. the payments and arrangements for product supply) which induced GUK to enter into the GUK Agreement:

> "… it was a loss of confidence on the part of GUK that it was going to be successful in the substantive patent proceedings that were due to come on … in the middle of March [2002]."

99. We acknowledge that the grant of the interim injunction was unexpected: see para 29 above. That was the evidence also of Ms West, GSK's experienced patent attorney. Apparently, it had hitherto been considered that the 'adequacy of damages' test favoured the refusal of such interim relief. But we do not accept that it led to a significant change of outlook or loss of confidence in its substantive prospects on the part of GUK. We reach that conclusion primarily on the basis of the contemporary documents and events. On 24 October 2001, the day after the Court hearing, Mr Eddie Hart, the Managing Director of GUK, wrote an internal email to some of his colleagues in GUK and Merck, stating:

> "Dear Team,
>
> You will by now no doubt have heard about the court's decision yesterday to injunct GUK against selling Paroxetine before the actual infringement case now scheduled for March next year. The court's reason for this centred around the judge's inability to decide whether our product did indeed infringe GSK's patent. As a result he ruled that IF it did GSK was likely to lose far more than GUK therefore on the balance of convenience he decided that GUK would have to wait until the court's decision in March 2002. We are confident that we do not infringe and will therefore be able to launch next year AND claim substantial damages from GSK. This information is for you only and should not be discussed with customers at this stage. We will discuss further at the next sales meeting.
>
> Going forward you may also be aware that Norton have signed an agreement with GSK to launch the GSK "generic" version of this product. We are not

> fully informed as to the nature of this agreement but it is very likely that Norton will be heavily controlled by GSK in the amount of product they can sell and the price they sell it at - probably a penny or two under the PI. Also, Norton are free to sub-licence the product to other generic players. We have been offered this deal but frankly the terms are not interesting to us. In fact they could well play into our hands. Assuming Norton launch limited quantities into the market in December [the earliest date we have heard] we will only have to wait a further three months to launch our own product which we know will be much more competitive than Norton.
>
> Additionally, it will be patently clear to our customers that Norton again are the generic spoilers in this regard in aiding and abetting a multinational company by preventing true generic competition and artificially managing the situation which can only harm the short-liners. This point should be clearly stressed.
>
> It is obvious for us that this is not the ideal situation but I firmly believe that we can turn it around to our advantage in 2002…"

The reference to March 2002 reflected Jacob J's direction for trial to take place the following March: see para 30 above.

100. Further, in a letter to sent to GUK's wholesalers on 29 October 2001, GUK stated:

> "With regard to Paroxetine as you may be aware we are still fighting to bring this product to the market as quickly as possible. We are confident that we have a non-infringing product and will win our legal case. It is my greatest wish to be able to supply you and break GSK's dominance and manipulation of the product via other 3rd parties. I will keep you informed of our progress."

101. We of course recognise that such an expression of confidence in a communication to customers must be viewed cautiously as GUK would clearly wish to appear optimistic. But the fact is that following the interim injunction, GUK continued to contest the litigation. It settled only the day before trial, after counsel had been briefed and, no doubt, the expert instructed.

102. Although Mr Urwin suggested in his witness statements made in the course of the CMA investigation that the injunction made him think that GUK's case was "weaker than I first thought", we do not find that plausible. As correctly reflected in Mr Hart's email in 2001, the interim injunction was granted on the basis of the balance of convenience after Jacob J expressly stated that he was "quite unable to decide the relative strength of the parties' contentions" as to either validity or infringement. GUK is a sophisticated company with

experience of patent litigation and had access to advice from specialist patent counsel. There was nothing in the decision on the grant of interim relief for six months that would rationally affect its assessment of the strength of its position. We reject as implausible Mr Urwin's assertions to the contrary which he made when interviewed over 10 years later by the OFT.

103. From about October 2001 onwards, there were meetings between representatives of GSK and GUK to discuss potential settlement, and in particular from late November 2001 GSK made a series of offers to GUK, in terms of a supply of a specified volume of product plus cash payments for "marketing", and GUK continued to press for better terms. The details are summarised in Table 3.2 of the Decision. GUK's approach is indicated by the internal email exchange over new year 2001/2002. On 31 December 2001, in an email sent to Mr Hart, Mr Urwin, Mr Howard Rosenberg, a patent attorney and the Head of Patents at Merck, and Mr Steve Self, the Head of Research and Development at GUK, Mr Saynor wrote:

> "… I would suggest the following actions:-
>
> – Provided that we [are] confident that we can win the case and seek damages on 18th of March then we should go ahead on our own.
>
> Although GSK's offer would deliver a similar bottom line (£5.6m v's £6m) this does not include recovery of active and any damage such an action may have with Sumika. Also we would also expect to recover substantial damages from GSK.
>
> The two remaining questions I now have are :-
> - How likely are we to win? …Howard
> - How soon will BASF or others be behind us? … Steve."

104. Mr Urwin wrote later the same day to Mr Rosenberg, copied to his colleagues:

> "Howard,
>
> Richard and I were taking their offers until the last minute before Christmas .....but their final offer was still not acceptable.
>
> Richard and I will discuss early in the new year ....
>
> But, as long as you remain confident of winning [although there are no guarantees] .... we must push for the best deal we can .... and that means [under scenario 2 - which is the option under discussion] that we need the API covered - plus a decent profit - otherwise we should puch [*sic*] on with the case for ultimate launch."

105. On 2 January 2002, Mr Self sent his comments, specifically "Re: paroxetine UK". He responded to Mr Saynor's first question, stating:

> "court cases are a bit of a lottery…. I am 110% confident that we will present the best case… there is always a small chance that despite the evidence the court decides against us."

He went on to express his preliminary views as to which rival companies might pose a threat, but said he would look into that further.

106. The same morning, Mr Rosenberg replied, under the broader heading "Re: paroxetine UK and elsewhere":

> "Whilst I am confident of winning in the long run...that is the operative word...long. GSK will delay, if thay [*sic*] can, when it suits them and alternatively push for deadlines to give us pressure. Obviously we will have to cope with all of this...and ultimately we will win:-
>
> a) the anhydrate patent is invalid, we can prove that now
>
> b) the tablet patent is invalid or could be restricted to hemihydrate only.
>
> c) the hemihydrate patent is more difficult to knock out, but possible. If GSK argue that there are traces of hemihydrate in our product, whilst again I think we can win it could take a long time going through appeals etc. to get the landmark ruling that something less than 1% is irrelevant....in each country.
>
> Now, we are quite prepared to do this...certainly the trace impurity legal work for 'c)' is relevant to all products (flecainide in USA, polymorphism in other products etc)....but it would be nicer to get a world settlement along the 'licence' idea, where we sell ours and theirs until the USA is resolved. Is it possible to have this discussion with GSK?"

107. In the light of those comments, Mr Saynor contacted Dr Reilly at GSK later that day, rejecting GSK's latest settlement offer, as recorded in an internal email from Dr Reilly to his colleagues and GSK's solicitors:

> "I have received confirmation from Richard this afternoon saying that Merck Generics have rejected the offer of a commercial settlement for Paroxetine. They are clearly only interested in a European deal. I could not negotiate away their requirement for assurances of further European deals.
>
> As they have now rejected our final offer they will now go to court."

108. We would emphasise that these exchanges took place after GSK had commenced its separate infringement action against GUK regarding the Hemihydrate Patent. In our judgment, they do not indicate that GUK was

anxious or determined to settle the case. On the contrary, they show that while GUK of course recognised that all litigation carries a risk and that like most businesses it would be happy to settle if the terms were commercially satisfactory, if it could not get a sufficiently attractive deal it was ready to press on to trial.

109. The issue of settlement apparently resurfaced in February 2002, following discussion between GSK and Merck over a separate settlement in the Netherlands. GUK placed strong reliance on three emails from Mr Urwin: two sent on 12 March 2002, the day before the GUK Agreement was signed, and the third sent a month later, on 12 April 2002. The first, to Mr Saynor (and copied to various colleagues) discussed how a settlement should be presented to Sumika, the Japanese company from whom GUK was going to take supplies of the paroxetine API for its generic product, and how much compensation they would have to be given. Mr Urwin there stated:

> "Bear in mind that the only reason we are contemplating a distribution agreement with GSK is because there is a real chance we may not prevail in the courts … and Sumika needs to understand this very clearly. If we did not prevail, then we would not be buyoing [*sic*] any API in the short term."

110. The second was to Mr John Montgomery, who was the head of Merck's operations in Australia (called Alphapharm) where it was selling generic paroxetine:

> "John,
>
> In case nobody else has been keeping you informed, discussions with GSK have restarted re the above [i.e. paroxetine]. We have a real concern that we may not prevail in the patent case – so a settlement and local distribution agreement seem to be the best way to go – provided the numbers are right."

111. The third email was to Mr Cecil Taitz, the Commercial Director of GUK, which included the following passage:

> "We also need to think about Sumika ...I think they are making some kind of proposal - so we cannot react until we see that. Meanwhile, the following to consider with them:
>
> a. We have already bought 1000 kgs from them
>
> b. We are committed to a further 500kgs [with price still to be agreed - but a lot lower than the first 1000].

> c. We were injuncted - and may never have prevailed i.e. there was a risk that we might never have launched in the UK [hence the settlement].
>
> d. We bore all the risk of the API ... and all the expenses of the legal action. They did neither [but did develop the API].
>
> e. We would not have launched at risk - which means a launch probably Dec 2003 earliest.
>
> f. If/when we launched - we had enough API to see us through to Dec 2004.
>
> g. The agreement is effectively to Q1 2004 ...and only maybe to end 2004 - at which point we may launch anyway?
>
> h. We do need to give them something ....but I think it is a 'good will' payment....
>
> i. Could you consider this and make a proposal?"

112. Viewed in the light of the overall discussions which we have summarised, we do not see these communications, having regard to their timing, context and wording, as altering our assessment of GUK's position set out at para 108 above. It is of course possible that something had emerged in the course of preparation for trial which had significantly changed GUK's evaluation of its prospects. But GUK did not choose to disclose the legal advice it received, and the contemporary documents in evidence, in our judgment, do not lead to that conclusion.

113. We should make clear that we do not regard the statement in the 12 April 2002 email quoted at para 111 above that GUK "would not have launched at risk" as an accurate reflection of the position. It was put forward as a point that could be made in negotiation with Sumika; but as we have already found, and was indeed not in dispute, if GUK had not been injuncted it had indeed been ready to launch at risk. We should add that we were not impressed by Mr Urwin's explanation of the various emails in his witness statement of 25 July 2013 submitted to the CMA, which bears all the hallmarks of a carefully crafted document and on which, of course, he could not be cross-examined before the Tribunal.

(b) Alpharma

114. Alpharma started taking steps to enter the UK market in 2000. It sourced the paroxetine API from BASF and, as noted above, was planning to have the final tableted product manufactured in Iceland by Delta. In March 2000, Alpharma entered into a supply agreement with Medis, a subsidiary of Delta, for the Delta manufactured product. At the end of May 2001, Alpharma submitted an application for MAs for both 20mg and 30mg paroxetine, and two months later BASF commenced revocation proceedings as regards the Anhydrate Patent against GSK. On 29 April 2002, Alpharma obtained its UK MAs.

115. Initially, Alpharma was hoping for a successful outcome in the BASF proceedings, so that it would be ready to launch soon afterwards. The trial of the BASF action started on 14 March 2002, and on 11 June 2002, while judgment was pending, GSK started infringement proceedings against Alpharma based on both the Anhydrate and Hemihydrate Patents. Consistent with its strategy, Alpharma gave an undertaking not to market or sell a product pending judgment in the BASF proceedings, as embodied in the order of Jacob J on 24 June 2002.

116. As noted above, in the judgment in the BASF action handed down on 12 July 2002, Pumfrey J held that the process claims 10(i) and 11 in the Anhydrate Patent were valid, while revoking all the other claims. Shortly afterwards, on 1 August 2002, GSK amended its action against Alpharma to take account of that judgment and restricted its allegations to the process claim. It also dropped the allegation of infringement of the Hemihydrate Patent, apparently after experiments conducted in connection with the proceedings showed no hemihydrate in the sample tablets.

117. Following these developments, the critical issue for Alpharma was whether its final product infringed the process claim in the Anhydrate Patent. We accept on the evidence that Alpharma, unlike GUK, would not have launched at risk of infringement of the product claims in the Anhydrate Patent. Whether it would have launched once the only issue was whether its product infringed the

process claim is, we think, less clear. It could not do so, because at the hearing on 1 August 2002 Jacob J indicated that he would be prepared to grant an interim injunction to prevent marketing before trial, and Alpharma therefore renewed its undertaking on those terms. Its internal reaction to that development is apparent from an email exchange of 1-2 August from Mr Brendan Magrab, the Vice-President, Intellectual Property, of its parent company to various colleagues, including Mr Torben Laursen, its Sales and Marketing Director (Western Europe), stating:

> "Unfortunately, I have disappointing news to report on paroxetine. The judge essentially granted the injunction. The good news is that he ordered a prompt full trial on October 23.
>
> The judge was of the opinion that he did not to [*sic*] reach the evidence presented him on this case because a simple plant Inspection would end the matter on whether there was a displacement step in the process. Because he was inclined to grant the injunction, we simply represented that we would not market until the trial. We really had no choice, since he would have granted the injunction. He also suggested that an independent expert simply inspect the plant to see the process and that this would resolve the matter.
>
> Margaret[23] is optimistic that as soon as the independent expert sees the process, and presumably agrees with us, we can strongly urge SKB to drop the case. I have asked Margaret to identify possible experts and to see BASF's position on allowing the inspection. If we have difficulty securing cooperation, we will need business pressure at the highest level to get their help. I have also asked Margaret for an estimate of legal costs.
>
> We should also discuss tomorrow our options including the effect on the market opportunity of this delay, new discussions with Delta and the cost of pursuing this.…"

To this, Mr Laursen commented succinctly: "SHIT!!!!".

118. If Alpharma had decided not to launch its product while infringement proceedings were pending, then its interim undertaking only prevented it from doing what it was not prepared to do anyway. But the exchange we have quoted does not suggest that Alpharma was relatively indifferent to the grant of interim relief. On the contrary, we find that if the Court had not indicated a willingness to grant interim relief – such that Alpharma effectively had to give an undertaking – then Alpharma probably would have been prepared to launch

[23] Ms Margaret Lewis of Alpharma's external solicitors.

'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.

119. On 2 September 2002, Ms Lewis of Alpharma's patent solicitors reported "some not so-good developments". These were that their own expert had reported that he could not find acetone in the tablets he had tested, which suggested that the production could involve a displacement within the scope of the process claim of the patent.

120. On 4 September 2002, Mr Jakob Poulsen, the patent attorney at Alpharma ApS, provided a status report on the patent situation in various European markets. His paper also estimated the damages risk associated with launch in each of those markets. As regards the UK proceedings, in which he said trial was fixed to start on 22 October, he explained that the process claim concerns the use of a displacement agent in order to displace solvated solvent. Although Mr Poulsen had received Ms Lewis' email two days before, he continued: "BASF claims not to use this step, and are willing to allow an inspection, given the right confidentiality assurance." He also discussed the Dry Tableting Patent, and reported that Delta's process fell within that Patent so the question was its validity, which was under opposition in the EPO. He continued:

> "There is only a slim chance that the claims covering the anhydrate form will survive the opposition, but it might take years for EPO to reach a final decision after appeal. Margaret Lewis, Stephenson & Harwood, has further made an estimate of cost of 50 - 100.000 £ and of a time period of less than 6 months for obtaining a swift decision for the UK, if Alpharma chooses to institute invalidation proceedings for this jurisdiction. The patent does not seem to have been used for infringement proceedings in any jurisdiction yet."

121. Over the same period, Alpharma's Marketing Manager in the UK, Ms Helen Toogood, was in communication with Delta regarding production, which Delta was in the course of commencing. On 30 August 2002, she informed Delta:

> "It is true that we will be keen to launch as soon as we are in a position to do so legally, so please proceed with the packing run this weekend as you have planned."

122. On 2 September, Ms Toogood consulted Mr Andrew Collier, the Director of Sales and Marketing, asking whether Delta should be asked to halt production, given that they were already producing what amounted to six months' stock. Mr Collier responded that it was difficult for him to comment given "the uncertain legal position", but that he assumed Alpharma was honour bound to accept the order already placed.

123. From a further report of Mr Poulsen dated 12 September, it is clear that Alpharma and its lawyers were preparing hard for trial, and that BASF and Delta (neither of which was a party to the proceedings) had agreed to disclose their processes which, so Mr Poulsen said, "should work to our benefit". He further reported that the most recent analysis at Delta showed "acetone is present at least immediately before tabletting." Finding retained acetone was contrary to the displacement step involved in the process claim. But he also said that it was proving difficult to keep to the 22 October trial date (with the trial estimate of 3-4 days).

124. On 24 September, Mr Robert Wrobel (who was described by the CMA as the Chief Legal Officer of Alpharma Inc) wrote to Mr Carl-Aake Carlsson an email, then copied to various colleagues, in the following terms:

> "My general thoughts on an approach to Paroxetine is that we should make a proposal to Glaxo along the following lines:
>
> 1) We would agree to delay a launch of the product until a date which is later than the October trial date but sooner than October of 2003 (the assumed date of a appellate decision on Paroxetine). For example; perhaps April of 2003.
>
> 2) The Glaxo case would be terminated and Glaxo would agree not to challenge our April 2003 launch.
>
> 3) As a part of the termination of the case, we would withdraw our claim for the damages caused by Glaxo's filing of its request for injunction.
>
> We would receive an immediate payment from Glaxo in consideration of our agreement in (1) and (3) above. I would suggest that the amount of payment we propose should be based upon the profits which will be made by Glaxo by further six months of exclusivity rather than our launch profit model."

This appears to have been the genesis of the discussions which Alpharma then initiated with GSK.

125. Mr Laursen then met Dr Reilly on 1 October. He reported on the talks to his colleagues the same day, in an email in which he described Dr Reilly as the person at GSK "in charge of concluding deals for their tail-end products on a European level. This includes deals for products coming close to patent/exclusivity period expiry." The text of this important email merits almost full quotation:

> "We started out agreeing that both parties potentially can benefit from an out-of-court settlement of the dispute, and it will be beneficial to conclude talks within the next app. 3 weeks. Mark Reilly stated that GSK was very convinced that their intellectual property rights can keep generics out of the UK for the next 12 - 18 months. I challenged this long period and we agreed that obviously this was uncertain and we also agreed that Alpharma was ahead compared to the competitors.
>
> The highlights of the talks are:
>
> GSK prefer a settlement for 12 - 18 months consisting of a lumpsum and certain ongoing (monthly) payments. We would refrain from launching in this period and acknowledge the IP of GSK and all legal activities between the two companies would be stopped. I promised to come back with a calculation of what these figures can be.
>
> He understood the value of an early entry by us compared to any other competitor (except IVAX who are on the market with GSK product). Consequently this must be factored into a contract. GSK wants to supply product to us if we enter. They want to attack all non-GSK product entering the market, and he stated that he would struggle to get a contract approved by the legal department in which we can launch a Delta product at a later stage. I asked him to think this over again - an issue for further discussion.
>
> We agreed to meet again in the afternoon of Friday 11."

126. Unsurprisingly in the light of this discussion, the next day, Mr Laursen suggested that Alpharma cancelled all orders of paroxetine, adding: "This thing will draw on for a very long time ….."

127. At some point between 12 September and 11 October, the trial date of 22 October was vacated and refixed for December. It appears that this was to provide time for GSK to carry out an inspection at Delta's plant before the trial. In any event, on 11 October 2002, the second negotiating meeting took place, between Mr Laursen, this time joined by Mr Magrab, for Alpharma, and Dr Reilly and Ms Robinson for GSK. Again, Mr Laursen's full report of the discussion merits quotation:

"Initially we stated that a settlement must have elements of compensation for:

The loss we have suffered since early July. We said the value was £ 2.5 m a month as our gross margin forgone. That situation was likely to continue well into January if we win in the December trial date.

Inventory we have in Iceland

Attorney fees

Image loss by not launching and relationship loss with Delta

All in all we said this figure was in the region of £ 20 m.

GSK said that figure was much higher than they anticipated. The key issues for them was:

Stay within the law and not making any settlement that can be counterproductive for them in other jurisdictions around the globe

Keep patent defence intact

Maintaining stability and predictability (they are also in the middle of budget 2003)

The settlement they will offer has the following elements:

An MA for the "version 2" of the GSK product (ie. a version without GSK imprints on tablet etc.). GSK will supply bulk for IVAX to pack in Alpharma packs. Launch around December 1st, 2002. They will be ready to offer 500,000 packs of the 20 mg 30 tabs pack at a transfer price of £8.45 per pack. They claim generic selling price is around £13.15. Andrew we have to look into this Monday morning!

All litigation is stopped

We are free to launch the Delta product when we want. Ie. when our competitors at a much later stage have penetrated all GSK defences, most notably the infamous tableting patent which they eluded to [*sic*] without being explicit.

GSK will offer a lump sum and/or monthly payment which can be turned into either a cross undertaking as part of the settlement or a promotional fee. We clearly have to negotiate this further, and decide the minimum we can accept.

GSK consider us the only serious threat right now, but will be ready to consider similar deals if others make a similar threat."

128. While the parties' lawyers continued to prepare for trial, as evidenced by the solicitors' correspondence of mid-October 2002, a final meeting between Mssrs Laursen, Magrab and Dr Reilly took place on 23 October 2002, at which Mr Laursen records that agreement was reached. Mr Laursen summarised the terms in an email the following day:

> "1. 12 month deal with option to prolong.
>
> 2. An MA for the "2nd image" of the GSK product (ie. a version without GSK imprints on tablet etc.). GSK will supply bulk for IVAX to pack in Alpharma packs. Launch around December 1st, 2002. They will be ready to offer 500,000 packs of the 20 mg 30 tabs pack at a transfer price of £8.45. The value of this offer is app. £2.5 m on a 12 month basis. We will receive profit compensation for any delays after December 1st, as time is short for artwork, packing, logistics etc.
>
> 3. £0.1 m promotional allowances per month. Ie. £1.2 m on a 12 month basis.
>
> 4. £3.5 million "other". For this amount we need input from Finance on ideal timing, so we can try to phrase the contract accordingly.
>
> 5. Exclusivity period on offer for a range of GSK products with current sales revenue of £11 – 12 m. Own manufacturing will be an option if we want to. Andrew and his team will work on the value proposition for this when we receive the details. Linked to this we will get £0.5 m which Brendan clever [*sic*] suggest to name "promotional allowance" in the contract to make it hard money."

129. Thereafter, the parties were engaged in exchanging and commenting on drafts of an agreement, which was finally concluded on 12 November 2002 in the terms described above: see para 41.

130. Considering Alpharma's position as it emerges from these documents, in our view they do not reveal any sense that Alpharma considered that it must settle at all costs. As with GUK, Alpharma was obviously aware of the litigation risk and, on the evidence before us, it is unclear how Alpharma assessed the final experiments made in preparation for trial. (It will be recalled that Ms West said that GSK regarded them as inconclusive: para 38 above.) It is also obvious that Alpharma could not enter while its undertaking remained in place, but if Alpharma had prevailed at trial in December, we think it would have been unlikely to offer a further undertaking pending any appeal. In any event, the trial was expected to be a short one so that judgment would have been expected in about January 2003; and if GSK had lost but had been granted an injunction pending an appeal so that Alpharma could not enter before the appeal was determined, in those circumstances we consider that the appeal would probably have been expedited.

131. The trial would have concerned only the Anhydrate Patent. Although Ms Ford submitted that Alpharma had a lingering concern about the Hemihydrate Patent, that allegation had been abandoned by GSK in the proceedings, and she realistically accepted that if the position under the Anhydrate Patent had been resolved in Alpharma's favour, any such concern would not have deterred it from launching the product. As for the Dry Tableting Patent, our finding that Alpharma would have entered at risk absent its undertaking to the Court of June 2002 implies that it was not particularly concerned about that third patent, which indeed was later revoked by the EPO in May 2003.[24]

132. In short, if the parties had not successfully come to terms and Alpharma had prevailed in the litigation, we think there is little doubt that it would have launched its product in the UK, for which it had the necessary arrangements with Delta for production.

(c) GSK

133. On this question of potential competition, it is also appropriate to consider the perception of GSK. As regards GUK, GSK had no doubt that in the absence of injunctive relief GUK would have entered the UK market. Indeed, that was the basis on which it obtained the interim injunction. In his witness statement made in support of its application for interim relief in the Patents Court, Dr Reilly stated that GUK had informed one of GSK's customers that "a generic version of paroxetine will be available from [GUK] in the UK from mid-October [2001]." He discussed in his evidence the prospects of various generic companies wishing to enter the UK market (including specifically Norton [i.e. IVAX][25] but not Alpharma), and stated:

> "… I believe that there are a number of generic companies preparing to launch generic versions of paroxetine…. I would expect the introduction of [GUK's] generic paroxetine to result in the introduction of other generic products onto the [UK] marketplace shortly thereafter with a further wave

[24] See also the internal memo from Mr Paulson quoted at para 120 above. We note that the Dry Tabletting Patent was subsequently restored on appeal in 2006, although only after the decision of opposing suppliers to withdraw their opposition or not participate in the appeal: see para 10(3) above.
[25] Dr Reilly stated that he would expect Norton would wish "to be in the advanced guard of generic companies competing with Seroxat."

> following as little as 7 months later once relevant marketing authorisations are in place."

134. As regards Alpharma, in his witness statement dated 10 June 2002 made in support of GSK's application for interim relief against Alpharma, Dr Reilly reported that AAH plc, one of the UK's largest wholesalers of pharmaceutical products, had asked both IVAX and GUK for quotations for the supply of generic paroxetine to compare with a quotation AAH had received from Alpharma for supply from 1 June 2002. He proceeded to describe again the interest in the UK market shown by other generic suppliers who would "follow in [Alpharma's] wake" and stated:

> "If [Alpharma] is not injuncted until the trial of this action, the entire pricing structure of paroxetine will change."

135. Accordingly, we find that GSK clearly regarded GUK and Alpharma as potential competitors. Indeed, that is no doubt why the GUK and Alpharma Agreements each contain provisions precluding the generic company from entering the UK market. As the General Court stated in *Toshiba*, at para 231:

> "… it must be held that the very existence of the Gentlemen's Agreement provides a strong indication that a competitive relationship existed between the Japanese and European producers. As the Commission correctly notes, it is unlikely that they would have entered into a market-sharing agreement if they had not considered themselves to be at least potential competitors."

This passage was approved by the CJEU in dismissing the appeal: Case C-373/14P *Toshiba v Commission* EU:C:2016:26, para 33.

136. Moreover, we note that in its Notice of Appeal, GSK accepted "as a matter of ordinary language (rather than as a matter of legal principles applying to Chapter I infringements) that the generic companies were potential competitors of GSK, and that GSK considered them as such and perceived them as a threat" (para 6.38). The distinction with legal principle which GSK sought to make rested on the patent position. However, as regards GUK, we have found that in the absence of the Agreement it might have entered the market 'at risk', notwithstanding GSK's proceedings for infringement. As regards Alpharma, while we accept that it was more risk averse, we have found that after the product claims were held invalid by the judgment in the

BASF litigation on 12 July 2002 and the live issue was whether its product (made by Delta) infringed the process claims in the Anhydrate Patent, it probably would have entered 'at risk'. In any event, it is common ground that the outcome of the pending infringement trial was uncertain, so that there was a real, concrete possibility at the time when the Alpharma Agreement was concluded that Alpharma would have prevailed at trial about a month later and then entered the market.

137. However, GUK and Alpharma contended, with support from GSK, that the interim injunction/interim undertaking meant that irrespective of their intention or strategy, there was an insurmountable barrier to their entry and that they are therefore not to be regarded as potential competitors when assessing the Agreements for the purpose of competition law.

(d) The significance of the injunctions

138. In support of their arguments based on the interim orders, the Appellants relied strongly on the judgment of the General Court in Case T-360/09 *E.ON Ruhrgas and E.ON v Commission* EU:T:2012:332 *("E.ON Ruhrgas").* That was an appeal against a decision of the Commission finding an infringement by object by reason of a market sharing agreement between the leading German and French gas suppliers, respectively E.ON Ruhrgas ("Ruhrgas") and Gaz de France ("GDF"). In conjunction with a joint venture agreement to construct and operate a major pipeline importing gas into Germany and France, which became operational on 1 January 1980, the two parties agreed that they would not sell into each other's home market gas imported through the pipeline.

139. On the issue of whether Ruhrgas and GDF were properly to be regarded as potential competitors in each other's home market, the Court referred to the test for potential competition derived from the *Toshiba* and *Visa* cases: see para 92 above. As regards France, GDF had a monopoly on the import of gas under French law which was abolished only in 2003. However, the deadline for implementation of the first EU Gas Directive (Dir. 98/30/EC) requiring the opening up of the gas market was 10 August 2000. The Commission found

that some gas suppliers were able to penetrate the French gas market from that date to serve a limited group of customers. On that basis, the Court found that the Commission was correct to find that Ruhrgas was a potential competitor on the French market from 10 August 2000, but not before. As regards Germany, German competition law contained an exemption for a demarcation agreement by which undertakings agreed not to supply energy in each other's territory and for an exclusive concession agreement by a local authority for the operation of a gas distribution network, provided that the agreement was notified to the German competition authority; that exemption was abolished on 24 April 1998. The Court found that by reason of a series of such local demarcation agreements and exclusive concession agreements, the German market was characterised by the existence of de facto territorial monopolies until 1998. In those circumstances, the Court held that the Commission had been wrong to find that GDF was a potential competitor on the German market prior to 1998. The Court stated, at paras 103-104:

> "103. It is clear that that situation, which existed on the German market for gas until 24 April 1998, was likely to result in the absence of any competition, not only actual, but also potential, on that market. In that regard, it must be pointed out that it has been held that a geographical monopoly which local gas distribution undertakings enjoyed precluded any competition between them (see, to that effect, Case T-87/05 *EDP v Commission* [2005] ECR II-3745, paragraph 117).
>
> 104. Neither the contested decision nor the case file contains evidence capable of proving to the requisite legal standard that, if the agreement at issue had not applied and notwithstanding the characteristics of the German market for gas…, there would have been, up until 24 April 1998, a real, concrete possibility for GDF to enter the German gas market and to compete with the applicants as required by the case-law…"

140. However, in *E.ON Ruhrgas*, the legal position (in France) and the factual position (in Germany) which prevented the relevant party from entering the market was wholly independent of the parties themselves. Here, Mr Kon accepted, correctly in our view, that GUK and GSK were potential competitors prior to the grant of the interim injunction. He submitted that the situation fundamentally changed once the injunction was granted, since then it would have been a contempt of court for GUK to start selling paroxetine in the UK. Yet not only did the interim relief result from an application to the court by GSK, but GSK was free at any time to consent to the variation or discharge of

the interim order. If A and B are potential competitors based on objective criteria, such that a market-sharing agreement between them may be anti-competitive, we consider that it is misconceived to find that whether A and B continue to be potential competitors depends upon A's decision regarding a particular course of action (while it remains present on that market)[26].

141. Furthermore, there is the issue of duration. The interim injunction against GUK and the undertaking restraining Alpharma would have lasted only until judgment in the respective proceedings. The GUK Agreement was reached the day before trial, which nonetheless proceeded in the related proceedings involving BASF, so there are clear grounds for assuming that had GUK not settled the judgment of Pumfrey J of 12 July 2002 would have covered the GUK case as well as the BASF case. Even if it is assumed that with GUK's evidence the outcome on validity would have been the same (whereas on the basis of evidence from Apotex a different result was reached some 18 months later), it is wholly unclear whether GUK's product would have been found to infringe. Therefore in the absence of the GUK Agreement, the period of restraint would have been four months, and perhaps an additional period of some six months involved in an expedited appeal. But the duration of the GUK Agreement was for three years. Accordingly, the time over which GUK was prevented from entering the market by the interim injunction does not preclude it from being regarded as a *potential* competitor for the purpose of assessment of the GUK Agreement.

142. The situation regarding the Alpharma Agreement is somewhat similar. The Agreement was made on 12 November 2002 whereas Alpharma's prior interim undertaking was until judgment in the trial that would have taken place in December 2002. As that was a short trial concerning only infringement and the issue of displaced acetone, judgment could have been expected in January 2003; and if further interim relief had been granted pending an appeal then again we consider that appeal would have been expedited and determined within some six months. By contrast, the Alpharma Agreement was for a one

[26] We include that qualification since if A decided to exit the market then that would be an objective change which could mean that they cease to be potential competitors.

year term to 30 November 2003, subsequently extended by a further year to 30 November 2004.[27] Thus the exclusion of Alpharma as a supplier of independent generic paroxetine under the Alpharma Agreement lasted considerably longer than any potential interim relief.

143. Following the approach of the Commission Guidelines approved in the *Visa* case, we consider that as at the date of the respective Agreements, the period during which the parties would have anticipated that GUK or Alpharma would be prevented by the court's interim orders from entering the market was not such as to prevent GSK from taking account in its commercial conduct of the realistic possibility that it might lose at trial such that the generic company would thereafter be free to enter the market. Indeed, the fact that GSK entered into the Agreements, notwithstanding the interim relief it had obtained, demonstrates that GSK took into account the risk that it might lose at trial such that GUK and Alpharma would then be able to enter the market with independently sourced paroxetine. Both Agreements of course contain provisions expressly prohibiting the generic company from doing so: clause 7 of the GUK Agreement and clause 8 of the Alpharma Agreement.

(e) The *Lundbeck* judgments

144. Accordingly, we would find that GUK and Alpharma were as a matter of law and reality potential competitors at the time of the respective Agreements, notwithstanding the interim relief, and that the CMA was correct in reaching that conclusion. But this issue now has to be addressed in the light of the *Lundbeck* judgments.

145. The Danish company Lundbeck A/S ("Lundbeck") is, like GSK, a so-called 'originator' company engaged in the research and development, and then subsequent marketing and sale, of pharmaceutical drugs. Lundbeck produced an antidepressant called citalopram, which it marketed under the brand name "Cipramil". By 2002, Lundbeck's patents covering the citalopram API and

[27] Extension of the initial term was envisaged at the time the agreement was concluded: see para 128 above.

two processes for its production had expired, but between 1998 and 2001 Lundbeck filed applications for several patents for different processes for the production of citalopram. Two such patents were granted by the EPO, another (the "crystallisation patent") was granted by various national authorities including the UK in early 2002 (and later in 2002 by the EPO), and a fourth (the "film distillation patent") was granted by the UK and Danish authorities.

146. In 2002, Lundbeck concluded agreements concerning citalopram with four generic companies: Merck (GUK), Arrow Group A/S ("Arrow"), Alpharma and Ranbaxy Laboratories Ltd ("Ranbaxy"). The terms of each agreement were different, and it will be necessary to refer to some of them in more detail later in this judgment. But under each of them, it was recited that Lundbeck considered (or that there was a risk) that the generic company's product might infringe one or more of Lundbeck's patents, and by the agreement the generic company agreed not to sell its generic citalopram and Lundbeck agreed to pay significant sums to the generic company.

147. As noted above, the Commission adopted a decision finding that the agreements constituted 'by object' infringements of Art 101 and imposed significant fines; and by six simultaneous judgments, the General Court dismissed all the companies' appeals: para 85 above. Further appeals to the CJEU are pending.

148. One ground of appeal concerned the Appellants' contention that by reason of Lundbeck's patents, the generic companies and Lundbeck were not potential competitors. The General Court summarised the case-law derived from the *Toshiba, Visa* and *E.ON Ruhrgas* judgments, and then addressed the issue on the specific facts of the case. The long passage in the judgment in *Lundbeck* merits fairly full quotation:

> "121. Whilst patents are indeed presumed valid until they are expressly revoked or invalidated by a competent authority or court, that presumption of validity cannot be equated with a presumption of illegality of generic products validly placed on the market which the patent holder deems to be infringing the patent.
>
> 122. As the Commission rightly points out, without this being called into question by the applicants, in the present case it was for [Lundbeck] to prove

before the national courts, in the event that generics entered the market, that those generics infringed one of their process patents, since an 'at risk' entry is not unlawful in itself. Moreover, in the context of an infringement action brought by Lundbeck against the generic undertakings, those undertakings could have contested the validity of the patent on which Lundbeck relied by raising a counter-claim. Such claims occur frequently in patent litigation and lead, in numerous cases, to a declaration of invalidity of the process patent relied on by the patent holder… Thus, it can be seen from the evidence…that Lundbeck itself estimated the probability that its crystallisation patent would be held invalid at 50 to 60%.

…

124…in view of the factors recalled in paragraph 122 above, it must be found that the Commission did not commit an error in considering that Lundbeck's process patents did not necessarily constitute insurmountable barriers for the generic undertakings…which were willing and ready to enter the citalopram market, and which had already made considerable investments to that end at the time the agreements at issue were concluded.

125. It is indeed possible that, in certain cases, [Lundbeck] might have been successful before the competent courts and obtained injunctions or damages against the generic undertakings. However, it can be seen from the evidence in the contested decision as regards each of the generic undertakings that that possibility was not perceived at the time as a sufficiently credible threat to them. Thus Merck (GUK) has taken the view, for example, following the publication of the crystallisation patent, that the Natco citalopram was 'non-infringing', that 'none of the published patent applications…constituted a problem' and that, in the light of expert statements, it did 'not have a patent problem at all'….

126. In addition, it was not at all certain that applicants would have actually initiated litigation in the event that generics entered the market. The contested decision indeed acknowledges that the applicants had put in place a general strategy consisting in threatening infringement actions or bringing such actions on the basis of their process patents. Nevertheless, any decision to bring an action depended on the applicants' assessment of the probability that an action would be successful and that a marketed generic product would be held to be infringing. Yet they were aware that 'generic [manufacturers] could have produced citalopram by using the process described in [Lundbeck's] original compound patent…or they could have invested to invent an entirely new process'…. Furthermore, faced with possible counter-claims, Lundbeck knew that the crystallisation patent was 'not the strongest of all patents' and that it was considered by some of its rivals to be 'high school chemistry'….

127. Lastly, it must be observed that, in the present case, Lundbeck's original patents had already expired when the agreements at issue were concluded, and that the crystallisation patent had not yet been definitively granted in the United Kingdom, for the purpose of Article 25 of the UK Patents Act 1977, when the GUK United Kingdom agreement and the Arrow UK agreement were concluded. The grant of interim measures in favour of Lundbeck in the United Kingdom against Merck (GUK) and Arrow would therefore have been, if not impossible, at the very least unlikely in the event that those undertakings entered the United Kingdom market before that patent was granted. Consequently, it is unlikely that Lundbeck could have obtained

> injunctions against all of the generic undertakings, even if it had systematically brought actions against them. Likewise, the iodo patent was not granted until 26 March 2003.
>
> 128. It must therefore be found,…that in general the generic undertakings had several routes – constituting real concrete possibilities – to enter the market at the time the agreements at issue were concluded…. Those possible routes included, inter alia, launching the generic product 'at risk', with the possibility of having to face proceedings brought by Lundbeck.
>
> 129. That possibility represents the expression of potential competition, in a situation such as that in the present case where Lundbeck's original patents, concerning both the citalopram API and the cyanation and alkylation processes, had expired and where there were other processes allowing the production of generic citalopram that had not been found to infringe other Lundbeck patents, which the applicants themselves acknowledged in their reply to the statement of objections. In addition, the steps taken and investments made by the generic undertakings in order to enter the citalopram market before concluding the agreements at issue,… show that they were ready to enter the market and to accept the risks involved in such an entry.
>
> …
>
> 131. The case-law requires only that it be demonstrated that the generic undertakings had real concrete possibilities and the capacity to enter the market, which is certainly the case when those undertakings had made significant investments in order to enter the market and when they had already obtained MAs or had taken the necessary steps to obtain them within a reasonable period."

149. In all the circumstances, the General Court concluded that the Commission had rightly found that the generic companies were potential competitors of Lundbeck.

150. The Appellants and the CMA both submitted that the *Lundbeck* judgment supported their position. The judgment clearly held that the fact that the originator held various patents does not preclude a generic company which contends that the patents were invalid or not infringed from constituting a potential competitor. However, the Appellants argued that there are material differences in the facts of the present case which make it not merely distinguishable but which, applying the reasoning in *Lundbeck*, lead to the opposite conclusion:

(1) Lundbeck itself estimated that the probability of its crystallisation patent being held invalid was 60% (para 122);

(2) it was not certain that Lundbeck would have brought proceedings if the generic companies had entered the market (para 126) ;

(3) even if Lundbeck had started proceedings, it was very unlikely that it could have obtained interim relief to prevent entry onto the market (para 127); and

(4) some of the generic companies had entered the market and launched at risk (para 131).

151. While these were among the factors referred to as relevant by the General Court, it is almost always possible, when a conclusion reached in a judgment is based on a series of factors, to point to some differences in the facts of a subsequent case or the absence of one of the factors taken into account by the earlier court. The question is whether that difference is so material as to lead to a contrary conclusion.

152. First, as regards Lundbeck's view of the strength of its patent, it is true that in the present case there is no contemporary evidence expressing GSK's internal view of the relevant paroxetine patents. But Lundbeck's estimate of invalidity related only to its crystallisation patent. There was no evidence in the Commission's decision of its views concerning the other three patents on which it was relying, and the recitals to several of the infringing agreements referred to the other patents. More particularly, the agreement with Ranbaxy referred only to a dispute as to whether the Ranbaxy product infringed the amide and iodo patents and there was no suggestion that it might infringe the crystallisation patent. Nor was there any suggestion that the amide or iodo patents might be invalid. The issue dividing Lundbeck and Ranbaxy was infringement not validity, as to which both parties wished to avoid litigation: *Sun and Ranbaxy*, paras 14, 144. But the General Court adopted a closely similar overall analysis and reached the same conclusion as regards Ranbaxy on potential competition as it did with regard to the other generic companies.

153. Secondly, as regards commencement of proceedings, Lundbeck had in fact started proceedings seeking an injunction in the UK against Alpharma, and the

agreement between Alpharma and Lundbeck was concluded some three weeks later, following an internal email by a director of Alpharma recommending settlement which noted that the process of manufacture used for its products was now considered likely to infringe Lundbeck's patents, but that its "chances of success were reasonable" in mounting a defence of invalidity: *Xellia and Alpharma*, paras 15 and 85. But the General Court adopted the same analysis and reached the same conclusion as regards Alpharma on potential competition as it did regarding the other generic companies.

154. Thirdly, as regards interim relief, this was a factor considered, particularly as regards Arrow and Merck, but the General Court was referred in rather misleading terms to the judgment of Jacob J of 23 October 2001 granting interim relief to GSK against GUK since Lundbeck alleged that it meant that "a generic undertaking cannot enter the market before it has proved that its product does not constitute an infringement…": *Lundbeck* at para 240. The General Court considered that there was no explanation as to why Lundbeck preferred to conclude the costly agreement with Arrow rather than enforcing its patents by obtaining interim relief pending a favourable judgment at trial: para 263. The Court also found that there might be distinctions between the facts of the instant case and *GSK v GUK* which made obtaining interim relief more difficult: paras 260-262; see also *Arrow*, paras 169-172, and *Merck*, paras 137-139.

155. In our view, it is not altogether clear what weight in its overall assessment the General Court attributed to the absence of interim relief. But more generally, the Court emphasised that for parties to be regarded as potential competitors it is not necessary that entry should be possible in the short-term. The agreements made by Lundbeck were mostly for a year, although several were then extended. The Court stated in *Lundbeck*, at para 163:

> "… it must be recalled that, in order to establish the existence of potential competition, the case-law requires only that the entry to the market take place within a reasonable period, without fixing a specific limit in that respect. The Commission therefore does not need to demonstrate with certainty that the entry of the generic undertakings to the market would have taken place before the expiry of the agreements at issue in order to be able to establish the existence of potential competition in the present case, particularly since, as the Court of Justice has already held, potential competition may be exerted

> long before the expiry of a patent (see, to that effect, judgment of 6 December 2012 in *AstraZeneca v Commission*, C-457/10 P, ECR, EU:C:2012:770, paragraph 108)."

156. That indicates, in our view, that the block on entry imposed by short-term interim relief pending trial should not be regarded as precluding the generic company being regarded as a potential competitor. That is of course aside from our view as to the proper approach to interim relief when assessing potential competition: para 144 above.

157. Fourthly, it was only Merck (GUK) which had actually entered some of the national markets. Merck's Swedish subsidiary had sold on the Swedish market for five months: *Lundbeck*, para 235; and GUK sold its generic citalopram in the UK in the brief period 1-4 August 2002 between the expiry of the first extension to its agreement with Lundbeck and the conclusion of the second addendum agreeing a further extension: *Lundbeck*, para 217. However, the General Court did not in consequence apply a different analysis as regards the position of Merck (GUK) compared to the other generic companies. Far from demonstrating, as Lundbeck and Merck argued, that this showed that in most national markets Merck (GUK) was not a competitor, the General Court upheld the Commission's approach that demonstration of certain market entry was unnecessary for a finding of potential competition. The two occasions of actual entry were therefore relevant only as evidential support for the finding that Merck (GUK) had "real, concrete possibilities" to enter the market.

158. Finally, it is appropriate to refer to the General Court's observations, at para 171 of *Lundbeck*, in response to the argument that the generic companies could not constitute potential competitors at the time of the agreements since some of them lacked a MA, which could take between 14 and 25 months to obtain:

> "It must also be observed that potential competition includes inter alia the activities of generic undertakings seeking to obtain the necessary MAs, as well as all the administrative and commercial steps required in order to prepare for entry to the market …. That potential competition is protected by Article 101 TFEU. If it were possible, without infringing competition law, to pay undertakings taking the necessary steps to prepare for the launch of a generic medicinal product, including obtaining an MA, and which have made

> significant investments to that end, to cease or merely slow that process, effective competition would never take place, or would suffer significant delays, at the expense of consumers, that is to say, in the present case, patients or national health insurance schemes."

159. Accordingly, we do not regard the *Lundbeck* judgments as authority for finding that the generic companies were not potential competitors in the present case. However, we note that one of the grounds in the pending appeal against those judgments concerns the finding of potential competition. In those circumstances, since we have decided in any event to make a reference regarding other issues on these appeals, we think it is appropriate to include in the reference a question on potential competition, which can also ask whether and to what extent it is relevant that the generic company is subject to an interim court order.

(2) Did the GUK and Alpharma Agreements have an anti-competitive object?

160. All the Appellants challenged the finding that the relevant Agreement was a restriction 'by object'; to the contrary, they argued that the Agreements brought about pro-competitive effects. This was Ground 3 of GSK's appeal; Ground 2 of GUK's appeal; Ground 1 of Merck's appeal; Ground 1 of Actavis' appeal; and Ground 1 of Xellia/ALLC's appeal.

161. The CMA's overall analysis is summarised at the outset of Part 6 of the Decision. It is convenient to quote most of the material paragraphs in full:

> "6.3 In summary, the CMA finds that the GUK-GSK Agreement and the Alpharma-GSK Agreement reveal, in and of themselves, a sufficient degree of harm to competition and therefore had the object of restricting competition. GSK paid GUK and Alpharma to remove the risk that they would enter the UK paroxetine market independently of GSK during a specified period, and so offer independent generic competition against GSK. GUK and Alpharma accepted value transfers from GSK as compensation for their agreement to delay their independent efforts to enter the market. Those value transfers included cash payments, and the effective transfer from GSK of profit margins by means of agreements permitting the supply of restricted volumes of product to the market in place of GSK. The appointment of GUK and Alpharma as distributors of GSK's paroxetine provided a means of transferring value from GSK to GUK and Alpharma, with no increase in the level of competition facing GSK in the relevant market.

6.4 The harmful consequence to be expected from this type of coordination in the pharmaceutical sector is that the potential for effective competition against the incumbent is, in essence, 'bought off'. Instead, under the objectionable arrangement, the parties share the profits from sustained high prices, while customers and consumers are deprived of the potential benefits of substantial price decreases.

6.5 In more detail, the reason why it can be in the interests of an originator such as GSK to pay a potential competitor with the objective of inducing it to delay its efforts to enter the market with its generic product, can be explained as follows. For the originator, the risk of its patent being held by a court to be invalid or not infringed, multiplied by the very significant amount of profit the originator would lose if true generic competition were to emerge, could mean that it is commercially more attractive to pay the generic supplier to delay its efforts to launch its generic product, and in so doing share its monopoly profits with the generic supplier.

6.6 If the transfers on offer from the originator are sufficient, it may also be in the interests of a potential entrant such as GUK and Alpharma to accept those transfers as compensation for its agreement to delay it[s] efforts to launch its generic product. Putting competition law considerations to one side, such a deal will be attractive to the generic supplier to the extent that the payments or value transfers from the originator are greater than the returns that the generic supplier could achieve from continuing with its efforts to enter the market independently of the originator, multiplied by its perceived prospect of success.

6.7 Under such arrangements, both competitors (this is, the originator and the generic supplier) can be better off at the same time, because the profit the generic supplier could make from entering the market will be lower (and often considerably lower) than the profit the originator would be likely to lose if independent generic entry occurred (that is to say, total profits are higher before true generic competition emerges). This is because,…generic entry will tend to be quickly followed by a significant reduction in market share and/or price level of the originator product as a result of strong price competition from generic suppliers. It may thus make commercial sense for the originator to avert generic entry by making payments or otherwise transferring value up to the amount of the profit it expects to lose if generic entry were to occur. Both the originator and the generic supplier will be better off, as they share the originator's monopoly profits between themselves and defer the threat of true generic competition and the associated price declines.

6.8 The relevant consumers, however, are deprived of the potential to benefit from the significant price declines associated with true generic competition. The payments and value transfers serve to reallocate profits between the originator and generic supplier, but induce delays to the potential emergence of true generic competition (and the associated price declines) while failing to improve the degree of competition on the market. Such an agreement is not the result of competition, but of its opposite, that is co-ordination between competitors at the expense of the consumer."

162. This reflects the approach of Prof Shapiro, who was an advisor to the CMA during their investigation. He considered that if the payment or cash equivalent transferred from the originator to the generic company had no

legitimate explanation other than as consideration for the delay in the attempt to enter the market, then the agreement is objectively to be regarded as inherently restrictive of competition. What might constitute a legitimate explanation? Prof Shapiro explained that in his view this could be the originator's litigation costs, using that expression broadly to cover not only legal costs but also the management time and disruption involved in pursuing a patent infringement case which are avoided by reason of the settlement. It could also cover payment for action by the generic company to expand the market: e.g., by promotion of the drug to a market segment where the originator had hitherto been less effective. But if and to the extent that the "value transfer" cannot be explained in such ways, then in Professor Shapiro's opinion the inference is that it must be designed to avoid the potential for competition from independent generic entry, which would be expected to cause a dramatic decline in the price and thus benefit consumers. It therefore amounts to the sharing of the monopoly profits, which may of course be entirely rational for the parties as it is in their respective commercial interests (leaving aside any competition law issues).

163. Such settlements have commonly been referred to as 'reverse payment' settlements, on the basis that the payment is coming from the originator asserting patent protection to the generic company challenging those patents, rather than in the other direction, as would be the case where a potential new supplier paid a licence fee to the patent holder. In the present cases, since neither GUK nor Alpharma (nor indeed IVAX) had actually entered the market, the term is something of a misnomer since there was only one way which any payment in settlement would go (other than for costs), unless GSK had granted a licence. But the CMA determined that the Agreements amount to "pay-for-delay", i.e. that there was no other legitimate explanation for the consideration given by GSK than artificially to delay an attempt at market entry by the generic companies.

164. The CMA accordingly treated the Agreements as involving a form of market exclusion, like the agreement between the European and Japanese producers in *Toshiba* that the latter would keep out of the European market: para 91 above. The CMA held that its conclusion that this was a restriction by object was

supported by the internal documents which showed the subjective intentions of the respective parties.

165. The law on restrictions by object was recently considered by the CJEU in Case C-67/13P *Groupement des Cartes Bancaires (CB) v Commission*: EU:C:2014:2204. That concerned certain membership fees payable under the rules of the grouping of French banks involved in the issue of CB payment cards (used as debit cards and for cash withdrawal) in France. The Commission's finding that the imposition of those fees had the object of restricting competition, in particular from new members to the CB system, was upheld by the General Court. However, on further appeal the CJEU held that the General Court had erred in law regarding restriction by object. The CJEU explained, in essence, that:

(1) Certain types of coordination between undertakings can be regarded, by their very nature, as being harmful to the proper functioning of normal competition, such that there is no need to examine their effects, e.g. horizontal price-fixing cartels (paras 50-51).

(2) To determine whether an agreement reveals a sufficient degree of harm to competition to be considered a restriction 'by object' within Art. 101(1), regard must be had to the content of its provisions, its objectives and all relevant aspects of its economic and legal context. Further:

> "When determining that context, it is also necessary to take into consideration the nature of the goods or services affected, as well as the real conditions of the functioning and structure of the market or markets in question." (para 53; see also para 78).

(3) The parties' subjective intention, although not a necessary factor to establish a restriction 'by object', can be taken into account (para 54).

(4) Where analysis on the basis above does not reveal a sufficient degree of harm to competition, there is not a restriction 'by object' and it is necessary to consider the effects of the coordination to determine whether there is an infringement of Art 101(1) (paras 52, 58).

166. Relying strongly on *Cartes Bancaires*, Ms Kreisberger submitted that the Agreements here cannot constitute 'by object' infringements. She stressed that they were settlement agreements made with regard to pending patent proceedings, and that agreements of that kind have never before been held to be anti-competitive. She argued that without being able to ascertain that the generic company would probably have prevailed in those proceedings, the Agreements cannot be regarded as "by their nature" harmful to competition. This was especially when they enabled a degree of entry by the generic companies onto the market which those companies would not have achieved had they lost the litigation.

167. However, it must be emphasised that there is no exhaustive list of the categories of agreements that may constitute an infringement 'by object'. Thus, the fact that agreements of the kind in question here have never before been found to be anti-competitive is not in itself conclusive.

168. Moreover, the fact that it may not be possible to show on the facts that a particular agreement is likely to have an anticompetitive effect does not preclude it from being a restriction 'by object'. As the CJEU stated in Case C-32/11 *Allianz Hungária* EU:C:2013:160, at para 38:

> "… in order for the agreement to be regarded as having an anti-competitive object, it is sufficient that it has the potential to have a negative impact on competition, that is to say, that it be capable in an individual case of resulting in the prevention, restriction or distortion of competition within the internal market. Whether and to what extent, in fact, such an effect results can only be of relevance for determining the amount of any fine and assessing any claim for damages…"

169. *Allianz Hungária* was cited with approval by the CJEU in *Cartes Bancaires*, decided only 18 months later.[28] Unsurprisingly, we see no inconsistency between the two judgments, and *Allianz Hungária*, which was a reference from the Hungarian Supreme Court, is instructive. The CJEU considered the proper approach to a series of bilateral agreements between car insurance companies and car repairers who were also dealers, whereby the rates paid by

[28] And the President of the Chamber which decided *Cartes Bancaires*, Judge Ilešič, was the Juge Rapporteur in *Allianz Hungária*.

the insurers for car repairs differed according to the number of car insurance policies the repairer/dealer had secured on behalf of that insurer when acting as an insurance broker in its activity of selling cars. Rejecting the insurers' arguments that the agreements could not constitute restrictions 'by object', the Court noted that the agreements linked the remuneration for the car repair service to that for the car insurance brokerage, taking advantage of the dual capacity in which the repairers/dealers acted. The Court stated that it was notable that by such agreements the insurers sought to maintain or increase their market shares. In deciding the question of object, it was accordingly necessary to determine whether the agreements were sufficiently injurious to competition on the car insurance market, having regard to their economic and legal context. That would include consideration of the existence of alternative distribution channels and the importance and market power of the companies involved.

170. Restriction by 'object' therefore focusses on determining the potential effect of the agreement, having regard to its nature and its context, rather than on establishing on the facts what are, or were, its likely effects. That is why a horizontal price-fixing agreement remains a restriction 'by object' even if the parties can show that it was never observed and had no actual effect in increasing prices. Of course, that potential must be realistic and not fanciful and it must be clear that the potential effects would materially harm competition. The assessment may, therefore, involve some consideration of potential effect in the overall market context, and we do not accept Ms Kreisberger's submission that once it becomes necessary to engage in any factual assessment of effects, that precludes a conclusion that the agreement is a 'by object' restriction: cp *Allianz Hungária* at paras 47-48.

171. We accordingly consider whether the GUK and Alpharma Agreements were, given their terms and their economic and legal context, inherently harmful to competition, and consider also the intention of the various parties.

(a) The terms of the Agreements

172. We have summarised above the material terms of the GUK and the Alpharma Agreements, and the related Supply Agreements with IVAX:

(1) for the GUK Agreement, see paras 32-35 above;

(2) for the Alpharma Agreement, see paras 41-43 above.

Accordingly, we do not repeat that here, but draw attention to several aspects of those two Agreements, some of which are pertinent also to the IVAX Agreement (see paras 22-24, 34 and 44 above).

Volumes of paroxetine supplied

173. Pursuant to all the Agreements, GSK agreed to supply a significant but limited volume of generic paroxetine. Under the IVAX Agreement, the supply was direct from GSK to IVAX. Under the GUK and Alpharma Agreements respectively, that was achieved by way of GSK supplying those additional quantities to IVAX, which IVAX in turn supplied to GUK and Alpharma.

174. In the IVAX Agreement, clause 7.3 stated:

> "For technical reasons the quantities of the PRODUCT to be supplied to IVAX during the twelve month term of this Agreement shall not exceed seven hundred and seventy thousand (770,000) PACKS of the PRODUCT unless otherwise agreed."

"Product" was defined to mean 30 tablet packs of 20mg generic paroxetine manufactured by GSK.

175. Following conclusion of the GUK Agreement and the IVAX-GUK Supply Agreement, whereby GUK could purchase up to 750,000 packs of 30 x 20mg paroxetine from IVAX to be delivered in the GUK livery, the IVAX Agreement was amended to change the definition of "Product" to mean paroxetine in bulk form and a new clause 7.3 was substituted (clearly reflecting the additional volume agreed with GUK) as follows:

> "For technical reasons the quantities of the PRODUCT to be supplied to IVAX during the term of this Agreement shall be a sufficient amount of the PRODUCT to enable IVAX to manufacture one million five hundred and twenty thousand (1,520,000) PACKS net of any wastage in each CONTRACT YEAR…."

176. However, notwithstanding this wording, Dr Reilly could not suggest any technical limitation on GSK's ability to supply larger quantity to IVAX. Indeed, when the IVAX Agreement was further amended following the Alpharma Agreement, the quantity was increased to 2.02 million packs (similarly reflecting the additional 500,000 packs on which GSK agreed with Alpharma). In our view, the references to "technical reasons" were specious. The volumes simply expressed the commercial deal, taking into account the financial benefit to the generic company and the detriment to GSK by reason of the quantity of generic product that would be sold on the UK market as a result of the successive Agreements.

"Marketing Allowance"

177. The GUK Agreement provided for payment by GSK of a "marketing allowance" of £1.65 million p.a. for a three year period. The Alpharma Agreement provided for payment of a "marketing allowance" of £100,000 per month for the 12-month term. On the extension of the Alpharma Agreement for a second year, by the amendment agreed on 14 November 2003, the "marketing allowance" was continued at the same rate for the extended term.

178. However, Dr Reilly accepted that generic companies do not have to incur the significant expenditure on marketing to GPs, compared to an originator like GSK. Hence, in this case it was GSK which undertook the promotion of paroxetine for which most of the prescriptions were written generically: the generic companies could in effect piggy-back on that promotion. The figures ascribed to a "marketing allowance" in the Agreements can be compared with GUK's annual marketing budget at the time for all its products of £400,000.

179. In our view, these sums were not related to any expected marketing expenditure. Ms Ford indeed accepted that on behalf of Alpharma. In our view, these were simply convenient labels selected for what was part of the

overall financial consideration paid by GSK to the generic company under the commercial deal. The same conclusion applies to the so-called "promotional allowance" of £3.2 million which GSK agreed to pay IVAX under clause 5 of the IVAX Agreement. That sum was payable in instalments over the 12 months original term of the IVAX Agreement, and clause 5 notably stated:

> "In the event that this Agreement terminates before the twelve month period has expired other than by [GSK] pursuant to clauses 3.3 or 3.4[29], then all outstanding instalments shall remain payable for the remaining months during that twelve month period."

180. We find it remarkable, and somewhat revealing, that the parties chose in the formal agreements to designate these payments in a manner that we find was misleading.

The values transferred

181. The CMA found that by the GUK Agreement, GSK effectively undertook to make a value transfer to GUK of £21.3 million over the three year term, calculated as follows:

(1) The annual "marketing allowance" of £1.65 million.

(2) The purchase of GUK's stock of paroxetine for the US$ equivalent of £8.8 million, paid quarterly.

(3) A distribution margin of at least £7.5 million on the quantity of stock supplied (based on the assumption that GUK's sale price would be no less than the estimated PI price of £11.80 per pack).

See Decision, paras 6.91, 6.104 and fn 1713.[30]

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[29] Cl 3.3 allowed termination for unremedied breach of if either party is put into liquidation by the other; cl. 3.4 allowed termination if the other party came under control of a third party.

[30] In fact, the total would appear to be at least £22.3 million having regard to the guaranteed margin on GUK's sales of £2.85 million p.a.

182. Similarly, the CMA calculated that by the Alpharma Agreement and its subsequent renewal for a second year, GSK effectively undertook to make a value transfer to Alpharma of £11.8 million over the two years, calculated as follows:

(1) The "marketing allowance" of £100,000 per month.

(2) £3 million for Alpharma's "production and preparation costs for launch in the UK market".

(3) £0.5 million towards legal costs.

(4) A value of £500,000 through access to potential purchase of three other GSK products or an alternative means of achieving that value.

(5) A distribution margin of £5.9 million (based on the assumption that GSK was transferring to Alpharma the profit margin that GSK would have earned on the volume of product supplied).

See Decision, paras 6.155 and 6.164.

183. The £5.9 million at (5) above reflects the profit margin sacrificed by GSK but seems overstated as regards the value received by Alpharma since, as we discuss below, Alpharma appears to have sold paroxetine at a price similar to GUK and below the prevailing Seroxat price. Further, the £500,000 at (4) above for access to other products was extinguished under the Amendment to the Alpharma Agreement which provided an additional volume of paroxetine for the second year. However, the CMA found, and it was not disputed, that transfers even well short of the figures they calculated were significantly above the avoided costs of litigation and management time should GSK have contested the patent actions against GUK and Alpharma through to conclusion.

184. We consider that the CMA was correct to regard the margin which the generic company was likely to earn on the specified volumes supplied as part of the

consideration. The price at which GUK and Alpharma obtained GSK's paroxetine (through IVAX) was £8.45 per pack. So long as no other generic company was able to enter the market with an independent product, the generic companies could expect to sell the paroxetine supplied by IVAX for at least the PI price. Further, GUK and Alpharma were effectively protected against the risk of a price fall resulting from such independent generic entry. GUK received an express profit guarantee of £2.85 million p.a. under clause 4.3 of the IVAX-GUK Supply Agreement (for which GSK undertook a corresponding obligation to reimburse IVAX). Alpharma had the right to terminate the IVAX-Alpharma Supply Agreement on one month's notice in the event of independent generic entry (and its obligation under clause 7 of the Alpharma Agreement not to sell its own independent generic product would thereby cease); and in that event IVAX would reimburse Alpharma for up to two months' loss due to the market price falling below £8.45 per pack, up to £200,000 per month (for which GSK undertook a corresponding obligation to reimburse IVAX).

185. Moreover, attribution of a cash value to the specified volumes to be supplied was the way the parties viewed the matter at the time in their negotiation. For example, as regards GUK, Mr Richard Saynor the Sales and Marketing Director, wrote to his colleagues on 22 December 2001 summarising the latest offer received from GSK of a three-year agreement which he evaluated as follows:

> "Year 1
> £4m (Marketing Payments)
> +
> 520k Packs at £8.85 cogs (this will give gross sales of £6.2m and nett [*sic*] profit of £1.63m)
>
> Year 2
> £1m + £2m (if no European agreement has been made)
> +
> 520k packs @ £8.85
>
> Year 3
> £1m + stock as above.
>
> In summary over a 3 year term they 'guaranteeing'
> Gross sales: £18.6m
> Profit £12.89m

Nett less active costs @ £8.3m = £4.6m

+ any other deal done in Europe.

Having slept on this I am inclined to agree with your view that this is a poor return given the level of investment."

That offer was indeed rejected by GUK. Under the final GUK Agreement, the volume of supplies was notably increased to 750,000 packs p.a. and under the related IVAX-GUK Supply Agreement the price was lower at £8.45 per pack.

186. As regards Alpharma, the report by Mr Laursen to his colleagues on 24 October 2002 setting out the agreement reached with GSK the previous day, quoted above at para 128, notably described the volume of generic product to be supplied in the following terms:

> "They will be ready to offer 500,000 packs of the 20 mg 30 tabs pack at a transfer price of £8.45. The value of this offer is app. £2.5m on a 12 month basis. We will receive profit compensation[31] for any delays after December 1st, as time is short for artwork, packing, logistics etc."

187. Therefore, in addition to substantial cash payments, both the GUK and Alpharma Agreements incorporated the transfer of significant non-cash value.

Restrictions on entry

188. Both the GUK and Alpharma Agreements of course precluded the generic company from independent entry into the UK market, i.e. with its own generic product. That restriction was imposed through the linked Supply Agreement with IVAX, as follows:

- by cl 8 of the GUK Agreement, GUK agreed both for itself and on behalf of each member of the Merck group that during the currency of the IVAX-GUK Supply Agreement it would not (save with GSK's consent) make, import, supply or offer to supply paroxetine hydrochloride in the UK other than as purchased from IVAX under that Supply Agreement or marketed by

[31] The IVAX-Alpharma Supply Agreement indeed incorporated such a provision at cl. 5.1.

GSK in the EU.[32] A similar restriction on GUK was imposed by cl 2.2 of the IVAX-GUK Supply Agreement. The IVAX-GUK Supply Agreement had a term of three years and by cl 4.4 could be terminated in the event that the average selling price of all generic paroxetine (i.e. excluding Seroxat and PIs) for at least three consecutive months in the third contract year fell below £8.45.

- by cl 7 of the Alpharma Agreement, Alpharma agreed both for itself and on behalf of each member of the Alpharma group that during the currency of the IVAX-Alpharma Supply Agreement it would not (save with GSK's consent) make, import, supply or offer to supply paroxetine hydrochloride in the UK other than as purchased from IVAX under that Supply Agreement or marketed by GSK in the EU. The IVAX-Alpharma Supply Agreement was for a term of one year from 1 December 2002, although it appears that the parties continued to adhere to it in December 2003-January 2004, following the extension of the Alpharma Agreement for a second year. By cl 11.3, Alpharma could terminate the IVAX-Alpharma Supply Agreement by one month's notice in the event of the formation of a "Generic Market", defined as occurring when the monthly average price of paroxetine "sold by any company" in the UK (other than GSK and Alpharma) fell below £9.50 per pack of 30 x 20 mg tablets (or when a paroxetine 20 mg product was sold other than under GSK's MA).

189. Accordingly, under both the GUK and Alpharma Agreements, GSK transferred substantial value in cash and non-cash terms, and the generic company accepted a restriction on entry into the UK market with an independent generic product.

Settlement of the patent proceedings

190. Both the GUK and Alpharma Agreements were made in settlement of the pending patent actions between the generic company and GSK.

[32] In theory, GUK could therefore have become a PI trader without infringing the GUK Agreement.

191. Under the GUK Agreement, the action was stayed under a 'Tomlin' order, whereby GSK waived any claim against GUK and Merck under the Anhydrate Patent, and Merck/GUK agreed that GSK will be under no liability to them under its cross-undertaking in damages. The GUK Agreement provided (by cl 11) that on termination of the IVAX-GUK Supply Agreement "whether by effluxion of time or otherwise", GSK and/or GUK were at liberty to restore that litigation.

192. The Alpharma Agreeement stated (at cl 9) that it was in full and final settlement of all claims by GSK in its action against Alpharma. The parties agreed to a consent order dismissing the claim, on terms that GSK waived any claim for relief against Alpharma and Alpharma agreed that GSK would be under no liability under its cross-undertaking. The parties reserved all their rights in respect of Alpharma's product that was the subject of the litigation and the Agreement provided that on termination of the IVAX-Alpharma Supply Agreement "whether by effluxion of time or otherwise", the parties "may take such action as each sees fit."

193. Accordingly, under both the GUK and the Alpharma Agreements the restriction on independent entry by the generic company and withdrawal of its challenge to GSK's patent was effectively tied to the duration of the Agreement.

(b) The strength of the patents

194. The existence of GSK's patents is of course fundamental to the legal context of the Agreements, and was at the foundation of the Appellants' arguments. We use the term "patent strength" as shorthand to cover both the question whether the patent was invalid and whether it was infringed by the particular generic product.

195. The Appellants submitted that to find that the Agreements had an anti-competitive object it would be necessary to make some assessment of the strength of the patent and determine that GSK would have been likely to fail in the patent litigation, or at least to find that the parties thought at the time that

GSK was likely to fail. If it was the case, either objectively or in the subjective view of the parties, that a patent was unlikely to prevent independent generic entry and the originator then made a large payment to the generic challenger to abandon its challenge and keep out of the market, that would be a true "pay-for-delay" case and anti-competitive. But that, the Appellants stressed, was far from the case here.

196. GSK's submissions as to its actual perceptions of patent strength seemed to vary in the course of the appeals. By its Notice of Appeal and further in the opening submissions of Mr Flynn QC, GSK submitted that it believed that it had strong and legally valid patents, and that each of the generic companies considered that they were on the wrong side of the argument. On that basis, GSK felt it was likely to prevail in court but was aware that there is always a litigation risk and that nothing could be certain.

197. However, in his closing submissions, Mr Flynn somewhat shifted the emphasis to submit that it cannot be said that GSK's patents were weak or that it had no confidence in its patents. He acknowledged that it was not part of GSK's case on its appeal that it would probably have won the patent trials, but that this was not a case where GSK had sought by the Agreements to supplement a weak patent position.

198. In her evidence, Ms West acknowledged that for important patent cases GSK instructed outside lawyers and as the case approached trial it relied on the advice of the specialist Queen's Counsel it had retained. She also explained that on the question of infringement of a process patent (as opposed to validity), it was difficult to assess the position prior to getting disclosure: one could not do so simply by getting hold of the generic product and inspecting or testing it.

199. The GUK Agreement was concluded the day before trial, and the Alpharma Agreement was concluded a few weeks before trial. There was no evidence before us as to what disclosure showed regarding infringement in either case, and as regards the Alpharma product Ms West in her witness statement said that the inspection of Delta manufacturing plant in Iceland was inconclusive

and that "neither side, it appears, was certain as to the true position" following that inspection.

200. Moreover, none of the parties disclosed the legal advice they had received from counsel on their prospects prior to settlement, which was of course protected by legal professional privilege. In particular here, given the nature of the disputes and the proximity of the settlements to trial, we consider that this advice would have been the fundamental contemporary evidence establishing the view which they held at the time as to their prospect of success. In *Digicel (St. Lucia) Ltd v Cable & Wireless Plc* [2009] EWHC 1437 (Ch), Morgan J observed at [25]:

> "… if the defendants did not disclose the legal advice, they could hardly ask the court to infer that the legal advice supported the alleged beliefs. That would not be a case of drawing adverse inferences against the defendants by reason of the claim to privilege; it would instead be a case of not drawing inferences in their favour; the reason for not drawing inferences in their favour being that the material was simply not before the court and could not be assessed."

201. We respectfully agree with that approach. We recognise that GSK was well aware of the litigation risk and that the parties' views of the strength of the patents may have differed. We also appreciate that GSK had a lot to lose if the trials had gone badly. But taking all this into account, having regard to the context of the negotiations of the two settlements described above and in the absence of disclosure of the legal advice, we are not persuaded that GSK was as confident in the strength of its patents as Dr Reilly asserted.

202. We have considered the views of GUK and Alpharma regarding the strength of the patents in our assessment of the question of potential competition above. We found that while both companies were of course aware of the risks of litigation, neither believed that it was very likely to lose and settled on the basis of weakness.

203. The pending trials with GUK and Alpharma that were avoided by the settlements concerned only the Anhydrate Patent. It was argued that irrespective of the strength of that patent, GSK had also the Hemihydrate Patent. However, although the proceedings brought by GSK against

Alpharma initially covered both patents, at about the end of July 2002 the claim was amended to drop the allegation of infringement of the Hemihydrate Patent. The proceedings against Apotex which went to trial also concerned only the Anhydrate Patent, and after the judgment holding the Anhydrate Patent invalid and not infringed, GSK no longer sought to prevent generic companies entering the market.

204. Dr Reilly accepted in answer to a question from the Tribunal that if GSK had considered that the Hemihydrate Patent had provided an effective means to stop generic companies entering the market, GSK would have relied on it. But GSK never obtained even interim relief or went to trial on that patent. We therefore do not think it requires separate consideration. As for the Dry Tabletting Patent, although there is evidence that this caused some internal concern at Alpharma, that was only on the basis of the time required to obtain a decision that the patent was invalid, since it was regarded as a weak patent (and indeed was ultimately revoked by the EPO).

205. Accordingly, we approach the issues in this case on the basis that the strength of the Anhydrate Patent, which was the critical patent, was uncertain. There is no scope to assess the likelihood that either GSK or the generic challenger would have won if the respective cases had gone to trial. As we understood it, that appeared to be the position which GSK accepted by the close of the hearing. It was certainly the approach adopted by the CMA: see Decision, para D.8. On the evidence before us, we think that was correct.

(c) *Subjective intention of the parties*

206. We have already made reference to the parties' subjective views in some of the discussion above. However, the Appellants argued that the Agreements cannot be characterised as "pay-for-delay" since the consideration paid by GSK was not seen as an inducement to delay entry. In that regard, we consider separately the intentions of GSK, GUK and Alpharma.

GSK

207. Dr Reilly explained that the GSK had a European management team which directed overall strategy within Europe, and such a settlement agreement would have been one of many aspects discussed with them.

208. On the evidence, the first internal GSK reference to a settlement agreement of this kind apparently came in a slide presentation of 5 February 2001 entitled "Seroxat Patent Challenge". Addressing the challenge from Paroxetine – Anhydrate, the final slide reads as follows:

> "Paroxetine – Anhydrate
>
> - Norton Healthcare have confirmed source of anhydrous salt
> - Test required to ensure no patent infringement
> - Recommend establishment of supply agreement
> - Commence mid 2001 (in 2001 Op Plan)
> - Take-up molecule 10%, 20%, 30% in years 1-3
> - Generic price 75% MSP [Market Supply Price] to compete with PI
> - Supply price (per Augmentin model) 47% MSP
> - Sales/profit impact £2.3m/£7.4m/£13.2m/£16.8m"

209. Dr Reilly, who confirmed he was involved in preparing this slide, said that it was essentially a recommendation to the wider management team of possible ways of countering the threat from generic companies, and in particular Norton (IVAX). He accepted, after some equivocation, that it was recommending the conclusion of a supply agreement with Norton as a possible way forward, with initial projections of what negative impact such an agreement would have over four years (2001-2004) on GSK's sales/profit margin. Dr Reilly agreed that the bullets "Supply price…47% MSP" and "Generic price 75% MSP to compete with PI" amounted to a proposal that GSK's price to Norton could be set around 47% of GSK's market selling price, with a view to Norton selling at about 75% of GSK's price, as it was thought that at that level the generic companies could compete effectively with parallel imports. Dr Reilly said that at the time of this presentation it was just a strategy which was being put forward and which could have been rejected. He said that it was a recommendation for a UK management subteam headed by Mr Eddie Gray, then managing director of UK pharmaceuticals, at this stage for initial discussion in terms of how to move forward. However, we note that the price level in the presentation corresponds to what subsequently

was agreed in the IVAX Agreement, when the supply price to IVAX was £8.45 a pack at a time when GSK's list price was £17.76.

210. When asked about GSK's "Project Dyke", Dr Reilly said that this was a team set up to monitor and report on what was going on across Europe and was not concerned with developing strategy. However, there was an internal GSK document concerning Seroxat, which it seems clear dated from late 2002 and which Dr Reilly said he had not seen at the time. It references the "Dyke Project" as involving:

> "● Legal defence of patent rights
>
> ● Co-marketing agreements established with generic companies"

The "Strategic Objectives" are there described as:

> "● Defend Seroxat patent rights
>
> ● Implement a successful brand fragmentation strategy
>
> ● Optimise market share for paroxetine throught [*sic*] co-marketing strategies
>
> ● Continue to exploit exclusive spectrum positioning across Depression and Anxiety"

211. A subsequent section of the document states:

> "3. Co-Marketing and Patent Defence
>
> Seroxat continues to face the increasing challenge of false generics (anhydrate and mesylate salts) launching into the market prior to patent expiry in 2006…
>
> **Anhydrate** – Anhydrate has launched in most Scandinavian markets, Germany, Spain, Netherlands, Portugal and Austria.
>
> Strong co-marketing strategies have continued to sustain Seroxat volume both in these markets and others where anhydrate has approval. However, there are increasing pressures on pricing where anhydrate has been launched which will challenge the current European floor price for Seroxat in 2003.
>
> With a combination of heightened market awareness to all new registrations for either anhydrate or mesylate, legal and regulatory actions implemented immediately to defend our patent, and co-marketing strategies, all orchestrated through the Dyke project, Seroxat has successfully maintained sales in 2002 with only a 2% decline on 2001 performance."

212. Dr Reilly said that "co-marketing" means an arrangement whereby the different companies arrange that each will devote its marketing efforts to different sectors of the market, and not supply agreements of the kind concluded with the generic companies for paroxetine; and further that in his view this document is "misleading and wrong". But whether or not that is the usual meaning of the term, we have little doubt that "co-marketing agreements" here refers to supply agreements of the kind concluded in the UK with IVAX, GUK and Alpharma. That emerges from another document produced on 29 August 2002 by one of the named contributors to the document we have quoted above, Mr Miguel Sleeper, who was in GSK's European pricing group, where he clearly uses "co-marketing agreement" to refer to such a supply agreement, as Dr Reilly accepted (while maintaining that it was an incorrect use of the term). And we see no reason why the internal document from which we have quoted in the two preceding paragraphs, produced by among others the GSK's "Commercial Strategy Director – Europe", with its considered analysis of GSK's strategy for optimising the potential for Seroxat, should be regarded as presenting a false picture of the company's approach.

213. In his witness statement, Dr Reilly succinctly expressed the purpose of the Agreements as being "to settle the patent disputes and maintain the integrity of the patents". He explained that GSK realised that there is always a risk of losing in court, which could lead to a complete loss of patent protection: the Agreements served to avoid that risk. From GSK's perspective, the Agreements were "not ideal" but they served to "maintain stability" by ensuring a "controlled scenario", as Dr Reilly described it in his interview by the CMA, as opposed to "full generic entry". Moreover, since the Agreements involved the generic companies obtaining paroxetine manufactured by GSK as opposed to from a third party, they ensured that the volume of production at what was an almost dedicated factory in Crawley was maintained.

214. Although the supply to the generic companies under the Agreements was expected to have some effect in displacing PIs, which was a benefit to GSK, Dr Reilly said that this was not a main reason for entering into the Agreements: GSK would rather have dealt with the PI issue in other ways.

215. GSK UK Pharmaceuticals' 2003 Plan, which appears to have been produced in late 2002 (i.e. well after the GUK Agreement but shortly before the Alpharma Agreement) summarised the "Critical Success Factors" and "Key Sensitivities" for the coming year. The second of the three success factors stated:

> "Generic Paroxetine – Settlement has been reached with IVAX and GUK (Merck Generics) and a supply agreement has been established with IVAX. This is a key strategy to maintain market stability for Seroxat across the Plan period. In the plan it is assumed that one further party joins the supply agreement. The plan assumes that growth of the Seroxat molecule will achieve £4.3m, while the lost margin as a result of the supply agreement will be £14m."

216. A 'key sensitivity' faced by the business was expressed as follows:

> "Genericisation of Paroxetine Assumptions of supply agreements holding are high risk. Significant further margin erosion (£10m) is possible as further suppliers approach the UK market."

217. Dr Reilly was familiar with this Plan, and explained that the £14 million figure was their broad estimate of the financial downside resulting from the supply agreements reached and envisaged, based on the difference between GSK's selling price for Seroxat and the supply volumes and price (£8.45) to the generic companies expected under the agreements. He said that this loss to GSK was compared with the alternative if GSK had lost the patent proceedings and there had been unrestricted generic entry. Calculation of the £14 million figure would have taken account of the fact that GSK was discounting its list price by reason of the brand equalisation deals it entered into to counter PIs.

218. Dr Reilly said, in response to a question from Mr Glynn, that GSK would have had some documents backing up the £14 million figure for the estimated financial impact of a projected supply agreement with a generic company. Dr Reilly also said, in answers to questions from Mr Malek, that each time GSK entered into a particular Agreement, it made an assessment, and then once the Agreements were concluded their expected cumulative effect would have been taken into account in making projections for GSK's figures for the year. He explained:

> "What we were trying to do, of course, was look at what the overall impact would have been….the overall modelling was done in terms of what would the volume have been supplied? What would the margins be? How was the deal constructed? … there would have been a financial assessment done on it and the impact on this year's financials."

219. We can well understand that after so many years such documents have not been preserved. Nonetheless, in the light of this, it was unfortunate, to say the least, and inaccurate for GSK to have responded to the CMA's Notice of 23 March 2012 under sect 26 CA, stating:

> "GSK does not believe that any financial forecast documents were created in relation to the decision as to whether to enter into the Agreements."

220. Around the time that GSK's 2003 Plan was produced, in October 2002, Dr Reilly was involved in a series of negotiating meetings with the representatives of Alpharma. The details of those meetings emerge from the full email reports by Mr Laursen of Alpharma: see paras 117 to 128 above.

221. On the first meeting, of 1 October 2002, Mr Laursen's report (para 125 above) included the following:

> "GSK prefer a settlement for 12 - 18 months consisting of a lumpsum and certain ongoing (monthly) payments. We would refrain from launching in this period and acknowledge the IP of GSK and all legal activities between the two companies would be stopped. …
>
> [Mark Reilly] understood the value of an early entry by us compared to any other competitor (except IVAX who are on the market with GSK product). Consequently this must be factored into a contract. GSK wants to supply product to us if we enter. They want to attack all non-GSK product entering the market, and he stated that he would struggle to get a contract approved by the legal department in which we can launch a Delta product at a later stage."

222. After the second meeting, on 11 October 2002, Mr Laursen reported on the terms of settlement which GSK indicated it would offer: para 127 above. Mr Laursen's email notably stated that the "key issues" for GSK were:

> "Stay within the law and not making any settlement that can be counter productive for them in other jurisdictions around the globe
>
> Keep patent defences intact
>
> Maintaining stability and predictability…."

This summary of GSK's objectives is consistent with its evidence elsewhere and we have no reason to doubt it. Mr Laursen's email concluded:

> "GSK will offer a lump sum and/or monthly payment which can be turned into either a cross undertaking as part of the settlement or a promotional fee. We clearly have to negotiate this further, and decide the minimum we can accept.
>
> GSK consider us the only serious threat right now, but will be ready to consider similar deals if others make a similar threat."

223. Dr Reilly acknowledged that he could not remember all the details of a meeting held more than 14 years previously. He could however recall that GSK there offered a supply agreement to Alpharma. However, he said he was sure that they would not have offered to pay Alpharma a lump sum, although he accepted that there probably was a suggestion of monthly payments that could be expressed as a promotional fee. He could not recall reference to the cross-undertaking, and he indeed told the CMA in an interview in the course of its investigation that he was not really sure what a cross-undertaking means.

224. It is hardly surprising that Dr Reilly could not remember everything about this meeting. We do not think it really matters whether GSK there offered a lump sum or only monthly payments: it was clearly offering to make a substantial payment. Mr Laursen's contemporaneous email, written to report on the meeting a few hours after it took place, is likely to be a reliable record. Moreover, at the final meeting on 23 October 2002, at which the commercial deal was concluded, GSK agreed to pay a lump sum of £3.5 million. Mr Laursen significantly referred to that element in his email report (para 128 above) as:

> "£3.5 million "other". For this amount we need input from Finance on ideal timing, so we can try to phrase the contract accordingly."

In the formal Alpharma Agreement, that sum was expressed to represent as constituting (i) £3 million "in respect of the production and preparation costs for launch in the UK market by Alpharma of paroxetine hydrochloride anhydrate", and (ii) £0.5 million towards Alpharma's legal costs in the settled litigation.

225. Dr Reilly agreed that a one-off payment of £3.5 million was "quite a lot of money". He accepted, as perhaps is obvious, that GSK would not have agreed to pay £3.5 million if it had not thought it necessary to secure the deal.

226. While Dr Reilly was the senior figure from GSK conducting the negotiations with the generic companies, he explained that he did not have direct authority to conclude the agreements. He would report the proposals to Mr Eddie Gray and he expected that he in turn would report to Mr Chris Viehbacher, who led the European management team, and Mr David Redfern, the finance director for Europe. Dr Reilly would then get clearance from Mr Gray to proceed. Dr Reilly explained that this was done over the telephone, without any written note, provided that the proposed agreement was "within expectations" at GSK given the overall plan which had been approved. That was the case with the Alpharma Agreement and, it seems, with the GUK Agreement: no written notes or reports seeking approval for Dr Reilly to enter into the Agreements were produced. In our view, given the limit on Dr Reilly's authority, this is a strong indication that the two agreements followed GSK's strategy of countering the generic threat to its valuable paroxetine product.

227. On the basis of the contemporary documents, we find that on the balance of probabilities:

(1) GSK was alert to the risk of generic companies seeking to enter into the lucrative UK paroxetine market and adopted a strategy for meeting this threat.

(2) GSK's strategic response involved not only legal proceedings in assertion of its patents but also potentially entering into supply agreements with a generic challenger. GSK realised that it may have to enter into a number of such agreements. Although such a supply agreement involved the cost of giving up some market share to the generic challenger and might require financial payments to the generic company, GSK believed that this "controlled" entry would cause significantly less commercial damage than full generic entry.

(3) To achieve its objective of eliminating the risk to its patents and protecting its market, GSK was further prepared to offer substantial value transfers to a credible potential generic entrant.

(4) In addition to the value GSK committed to transfer to the generic companies, GSK was also foregoing the additional profit which it would have earned on the volume of its production which it agreed to supply (through IVAX) to the generic companies.[33]

(5) Although not strictly necessary to reach a conclusion on this for the purpose of these appeals, it appears that GSK's "Project Dyke" went beyond merely monitoring the threat from generic companies and responses from GSK's various local operating companies, but encompassed the consideration and coordination of its strategy.

228. In arriving at these conclusions we appreciate that as regards Apotex, the company against which GSK also commenced proceedings that culminated in GSK losing at trial on the Anhydrate Patent, GSK apparently held no settlement discussions and no such supply agreement was proposed. GSK's evidence was that it held no such discussions with Apotex since there was a "particular belligerence" by Apotex against GSK because of what had happened outside the UK. We therefore do not see that as disturbing our conclusions above.

GUK

229. As we have observed above, GUK concluded its settlement with GSK the day before the trial of the infringement and validity proceedings concerning the Anhydrate Patent would have commenced in the Patents Court.

[33] The calculation of this loss depends on the extent to which the sales by the generic companies of the product they received pursuant to the Agreements substituted for Seroxat or for PI product for which GSK UK would receive credit from its overseas subsidiary. By the time of the Alpharma Agreement, PI sales in the UK had largely been displaced, so virtually all Alpharma sales were in substitution for Seroxat sales by GSK.

230. The settlement came after a number of previous offers had been rejected. In particular, we note that the final level of supplies which GSK agreed to provide pursuant to the GUK Agreement (750,000 packs p.a.) was higher, whereas the cash payments were lower, than in the offer reported by Mr Saynor on 22 December 2001 (520,000 packs p.a.) which GUK had rejected: para 185 above. This demonstrates how GUK saw the value of the authorised generic supplies it would receive as part of the consideration for the agreement.

231. As Mr Kon recognised, the size of the consideration finally offered by GSK was clearly a relevant consideration for GUK in deciding to conclude the Agreement rather than going to court the next day. Mr Kon sensibly did not seek to distinguish between the various aspects of the financial benefits which GUK received. However, he submitted that GUK's motivation for settlement was also GUK's potential exposure in the patent trial and the prospect of losing. Although, for reasons set out above, we have rejected the suggestion that GUK felt very vulnerable or was desperate to settle, we accept that the uncertainty, and therefore the risk of losing, was a factor in its decision to conclude the GUK Agreement.

232. Mr Kon also contended that another factor in arriving at the payments was GUK's contingent claim under GSK's cross-undertaking in damages. GSK had of course given such a cross-undertaking to support the award of an interim injunction on 23 October 2001 (see para 32 above). The restraint had therefore applied for 4½ months to the date of the settlement. However, this claim was dependent on GUK succeeding at trial. Other than a letter to IVAX that made reference on a "without prejudice save as to costs" basis to the claim which GUK had on the cross-undertaking "should we win at trial", it is striking that consideration of the value of the cross-undertaking did not feature in any of the negotiating discussions between GSK and GUK, as reported in the contemporaneous emails. We think that is probably because any such value was entirely dependent, first, on GUK prevailing in the litigation, and secondly, as Mr Kon acknowledged, it is in practice difficult to recover damages under such a cross-undertaking. Accordingly, we do not consider, on the evidence, that this was a notable factor in GUK's assessment.

Alpharma

233. Ms Ford contended that the payments received by Alpharma should not be regarded as an inducement to postpone its effort to enter the market independently. She submitted that some of the sums received under the Alpharma Agreement related to GSK's cross-undertaking in damages. GSK initially gave a cross-undertaking on 24 June 2002 in return for Alpharma's undertaking not to enter the market pending judgment in the BASF proceedings; and that was renewed on 1 August 2002 in the hearing before Jacob J when, faced with the potential of an interim injunction, Alpharma undertook not to enter pending judgment in the Alpharma trial.

234. In that regard, Ms Ford relied on the report by Mr Laursen on the second negotiating meeting with Dr Reilly on 11 October 2002, where Alpharma's opening approach was that it must have compensation for the loss it suffered through being unable to launch its product in July and its legal costs. It was at that meeting that Dr Reilly said that: "GSK will offer a lump sum and/or monthly payment which can be turned into either a cross undertaking as part of the settlement or a promotional fee": see para 127 above.

235. However, when the deal was struck on 23 October, the lump sum of £3.5 million which GSK finally agreed to pay was simply referred to in Mr Laursen's summary of the terms as "other": para 128 above.

236. The first draft of the settlement agreement sent by GSK to Alpharma, expressed the total £3.5 million as comprising £0.5 million towards Alpharma's legal fees and £3 million as compensation for the destruction of Alpharma's stock of generic paroxetine. Alpharma amended that draft to express the £3 million as relating to GSK's cross-undertaking in damages. But GSK apparently rejected that approach since the further draft sent by GSK proposed that the £3 million was in respect of Alpharma's "production and preparation costs for launch in the UK market." That was the formulation which was accepted for the final Alpharma Agreement.

237. Alpharma was clearly keen to get the maximum value that it could from GSK as consideration for the settlement and it would doubtless have pointed out GSK's potential liability under the cross-undertaking when seeking to extract the maximum payment from GSK. However, we do not think that it makes any real difference whether or not Alpharma viewed the £3 million as in part relating to the cross-undertaking. As with GUK, the cross-undertaking was valuable only insofar as Alpharma would have won at trial and been able to enter the market with its own product. In other words, the prospect of recovery from GSK on the cross-undertaking was entirely dependent on Alpharma establishing that it was able to enter the market independently. We have no doubt that Alpharma, which was engaged in patent litigation with specialist legal advice, would have appreciated this. We therefore reject the submission, as expressed in Ms Ford's closing, that "Alpharma considered that it was entitled to payment from GSK in respect of the cross-undertaking in any event".

238. As regards the so-called "marketing allowance", although Ms Ford realistically accepted that this was not intended to cover the cost of any projected promotional activity, she suggested that it was really a discount off the purchase price of the paroxetine to be supplied from GSK pursuant to the Agreement. For this submission, Ms Ford relied on an internal email dated 25 June 2003, at the time when Alpharma was considering renewal of the Alpharma Agreement for a further year, from Mr Russell Howard, the Managing Director of Alpharma in which he asked Ms Toogood:

> "Helen, can you do a new business case Delta vs GSK volume, revenue and profit from Nov 03 until Dec 04. Look at cost price from Delta vs cost price from GSK with and without the £100k contribution. Look at volumes we could sell if not 'restricted' in supply – as current. Discuss with PF potential entrants that may be ready to enter the market, which will then help us model when market will form and what effect that will have." [34]

239. However, we think that the internal discussion within Alpharma exemplified by this email was on the basis of whether it should seek to extend the arrangement with GSK or seek to enter the market independently. That

[34] Delta was the supplier to Alpharma of independent generic paroxetine: para 38 above.

emerges clearly from an earlier passage in the same email, where Mr Howard summarised the question to be considered:

> "We have placed our final order for Paroxetine for delivery in October for November stock. Our contract with GSK terminates at that point. We need to, therefore, consider do we continue with this deal and if so what does the deal look like – remember they have been giving us a monthly marketing input of £100k. Or do we break the deal and go with Delta?"

240. As to that, Alpharma's decision understandably depended on assessing the value of extending the contract with GSK compared to possible gains from independent entry. Significantly, Alpharma did not view the proposed £100,000 a month as somehow related indirectly to the price GSK/IVAX was charging for the paroxetine but simply as additional financial revenue that would flow from an extension of the Agreement.

241. We therefore consider that it is artificial to ascribe to particular payments due from GSK under the Alpharma Agreement a consideration that did not relate to Alpharma's agreement not to pursue its effort to enter the market. In our judgment, the reality which emerges from the contemporaneous evidence as regards the original Alpharma Agreement was that this was an overall commercial deal, whereby Alpharma agreed to delay the attempt to enter with its independent generic product by fighting the trial, and GSK agreed to pay it substantial sums of money and provide it with a specified volume of GSK-manufactured paroxetine at a price which enabled Alpharma to earn significant profit. Save only that there was no immediately pending trial, the same applies to the extension of the Agreement. We therefore reject Ms Ford's submission that Alpharma was only weighing up the opportunity it had been offered by GSK to enter the market even before the Anhydrate Patent was invalidated. The assessment made by Alpharma was to contrast the profits it could make from that course as against the opportunity and risk of entering 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.

244. However, the question on these appeals is whether such an agreement is unlawful for the purpose of competition law. In addressing that, the patent position cannot be ignored, and this situation cannot be equated to a simple agreement for exclusion of a potential competitor from the market or for market sharing.

245. A patent amounts to a temporary right to exclude. To term a patent "probabilistic" only emphasises the fact that a patent can be declared invalid on a successful challenge. But a patent confers a right only to exclude products which infringe, i.e. which fall within the scope of the patent. Here, infringement was a particularly important consideration: it would have been the only issue in the Alpharma trial; and the final outcome of the Apotex proceedings was a determination of non-infringement by Apotex of a valid process patent.

246. Moreover, it may well be impossible (as in the present case) to discern whether a patent is weak without proceedings which challenge its validity: see the remarks of Jacob LJ in *Servier v Apotex Inc* [2008] EWCA Civ 445 where, after upholding the decision of the trial judge that the patent at issue was invalid, and "very plainly so", he remarked at [9]:

> "It is the sort of patent which can give the patent system a bad name. I am not sure that much could have been done about this at the examination stage. There are other sorts of case where the Patent Office examination is seen to

> be too lenient. But this is not one of them. For simply comparing the cited prior art ('341) with the patent would not reveal lack of novelty and probably not obviousness. You need the technical input of experts both in the kind of chemistry involved and in powder X-ray diffraction and some experimental evidence in order to see just how specious the application for the patent was. The only solution to this type of undesirable patent is a rapid and efficient method for obtaining its revocation. Then it can be got rid of before it does too much harm to the public interest."

In citing these observations we do not of course imply that we think that GSK's paroxetine patents were similarly without merit, but simply underline that a court hearing a competition case will generally be in no position to assess the likely outcome of hypothetical patent litigation.

(d) ***No delayed entry in view of the injunctions***

247. At the time when the GUK and Alpharma Agreements were entered into, GUK and Alpharma respectively were already excluded from the market by reason of the interim injunction (in the case of GUK) and interim undertaking in lieu of an injunction (in the case of Alpharma). Accordingly, it was submitted that the Agreements cannot be regarded as having had the object of achieving exclusion since they lasted no longer than the litigation would have lasted had there been no settlement, and therefore in the absence of the respective Agreement the generic challenger would in any event have been excluded from the market for that period (irrespective of whether it might then have succeeded at trial).

248. This argument self-evidently has no bearing on the IVAX Agreement, since GSK never obtained interim relief against IVAX.

249. We consider that this argument also cannot apply to the GUK Agreement. The restriction on GUK selling independent (i.e. non-GSK) paroxetine under clause 4 of the GUK Agreement lasted for three years from 14 March 2002 since it was tied to the IVAX-GUK Supply Agreement. Clause 4.4 of the IVAX-GUK Supply Agreement stated:

> "In the event that the Market Price per Pack falls below £8.45 (exclusive of VAT) *for at least three consecutive months in the third Contract Year* (or any time thereafter) ("the Period") then either party may following expiration of the Period, terminate this Agreement with immediate effect on serving written notice." [Emphasis added]

Accordingly, GUK could not terminate the IVAX-GUK Supply Agreement before 14 June 2004 in any event.

250. The trial in the GUK proceedings was due to commence on 14 March 2002 and Pumfrey J's judgment in the joined BASF proceedings was given on 12 July 2002. The minimum duration of the restriction on GUK under the GUK Agreement was therefore much longer than any interim relief that would have continued in the proceedings, even allowing for a potential appeal.

251. Moreover, clause 4.4 provides a further reason why this submission cannot avail GUK. The basis for the interim injunction against GUK was to protect GSK against the damages it would suffer from the dramatic fall in its market price for Seroxat that would be caused by GUK's entry on the market with an independent generic product. The same price consequence would of course arise from independent entry by another generic company, and were that to occur the justification for the interim injunction would be extinguished. However, irrespective of such independent entry, under the GUK Agreement GUK was contractually prevented from supplying its own generic product on the market before June 2004. This indeed is precisely what happened. When the Apotex generic paroxetine came on the market in mid-December 2003 following Pumfrey J's judgment in the Apotex trial, the price came tumbling down and other generic entry soon followed. However, GUK was prevented from competing with its independent paroxetine and remained restricted as to the volume of GSK-sourced paroxetine it could offer. Almost as soon as it was contractually able to do so, on 25 June 2004, GUK served notice terminating the IVAX-GUK Supply Agreement, which in turn brought the restriction on GUK, and the GUK Agreement itself was terminated a week later, on 1 July 2004.

252. Accordingly, the restriction imposed by reason of the GUK Agreement had a materially longer duration than any interim injunction. Although the second reason set out above is not found in the Decision, that does not preclude it as a basis for rejecting this argument advanced for GUK and Merck on their appeals. The duration of the restriction on GUK is manifest on the face of the GUK Agreement and related IVAX-GUK Supply Agreement, and is not

affected by any extraneous evidence. We found the arguments of Mr Flynn and Mr Kon that we should not place any weight on the wording of clause 4.4 wholly unpersuasive.

253. As regards the Alpharma Agreement, the submission that there was no consequent delay in entry was advanced in particular by Mr O'Donoghue. It is correct that the position in this respect was different under the Alpharma Agreement from the GUK Agreement. Although the restriction on Alpharma was similarly linked to the duration of the IVAX-Alpharma Supply Agreement, that agreement provided, in clause 11.3:

> "Alpharma shall be permitted to terminate this Agreement upon one (1) month's written notice to IVAX upon formation of the Generic Market or upon demise (whether by invalidation, surrender, abandonment or otherwise) [of the process claim under the Anhydrate Patent]."

Alpharma accordingly served notice, as it was entitled to do, on 13 January 2004 to terminate the IVAX-Alpharma Supply Agreement, following the entry of Neolab and Waymade with the Apotex product. As the Alpharma trial would have taken place in December 2002, it was submitted that even if Alpharma had won, since interim relief would probably have been extended to cover the period of an appeal, the restraint under the Alpharma Agreement did not last longer than the likely period of interim relief in the absence of a settlement.

254. If, following a short trial on infringement alone, interim relief had been continued pending the decision on appeal, we doubt that the appeal would have taken a year, since in those circumstances it would probably have been expedited. Nor is it at all clear that if GSK had lost on infringement on the facts at trial, it would have sought interim relief for the duration of an appeal. We think that would have depended on the legal advice it received on its prospects in the appeal, and we note that after GSK lost at trial to Apotex and appealed, it did not seek to renew its interim relief against Apotex for the duration of that appeal. Therefore, viewed objectively as at the time when it was entered into, we consider that the initial one year term of the Alpharma Agreement would have been likely to exceed the duration of interim relief.

255. Moreover, competition law looks at the substance not the form. Although not included in the contract as signed, the resolution of the negotiation on 23 October 2002 was to have a "12 month deal with option to prolong": para 128 above. By amendment agreed on 14 November 2003, the Alpharma Agreement was duly extended by a further year to 30 November 2004. We therefore think it is appropriate to view the Alpharma Agreement as extended and not for its original one year term. It cannot be right that parties could contend that their agreement or arrangement involves only a short-term impact because contractually it has a short duration, notwithstanding that they anticipated that it would be repeatedly renewed. Nor can the eventual outcome of the Apotex litigation affect the objective assessment of the duration of the Alpharma Agreement as at the time the Agreement was entered into and then amended. If GSK had thereafter reached an analogous settlement with Apotex, there would have been no Apotex trial at all. It might be in the commercial interest of an originator holding a valuable patent to reach successive settlements by payment to each generic company which mounted a credible patent challenge. Accordingly, the Alpharma Agreement, as extended, substituted a contractual restriction on Alpharma entering the market due to last until 30 November 2004 for the interim undertaking which would have continued only until judgment in the Alpharma trial due to take place in December 2002 (and possibly until determination of any subsequent appeal: see para 254 above). In our judgment, the object of the Alpharma Agreement must be assessed on that basis and it was framed so that it could last well beyond the duration of any interim relief.

(e) ***Settlement of litigation***

256. All the Appellants emphasised that the GUK and Alpharma Agreements were made in settlement of litigation, an objective which should be seen as desirable. They were inherently a compromise, and such a compromise may often involve a payment from one party to the other.

257. The CMA seeks to stress in the Decision, as it did in argument on the appeals, that it is not opposed to settlement and is not contending that any settlement of patent litigation is necessarily anti-competitive,[35] or that if GSK did not capitulate completely the parties would have to fight their respective case through trial. In that regard, the CMA pointed to alternative forms of settlement, in particular a patent licence in return for royalty payments; or an early entry agreement, whereby the generic company was granted a right to enter before the expiry of the patent period: Decision paras 7.56, 7.109. The level of royalty in the former case, or the date of permitted entry in the latter case, would be a negotiated position taking account of the parties' perceptions of the strength of the patent. But in either case, the outcome would lead to independent generic entry and thus in the CMA's view a more competitive market to the benefit of the consumer.

258. The Appellants challenged this approach, submitting that GSK was clearly not prepared to countenance either of those forms of settlement. GUK indeed considered in late November 2001 proposing a royalty based agreement so that it could sell its independent generic product, and may indeed have proposed that to GSK, but the idea did not bear fruit. Alpharma, for its part, before it met GSK for negotiation, considered the possibility of an 'early entry' agreement, to permit it to enter with its independent product in c. April 2003: see Mr Wrobel's email of 24 September 2002 at para 124 above. It seems that this suggestion was then put forward in the first negotiating meeting with GSK on 1 October, but it evidently got nowhere: para 125 above.

259. In his evidence, Dr Reilly said that neither of these alternative forms of settlement was a viable option for GSK. In his witness statement, he said:

> "… from a commercial perspective, if GSK had allowed independent entry significantly in advance of patent expiry in these settlements that would have sent a very powerful signal to other potential infringers that GSK lacked the determination to defend its patents. The danger would then have been that this would undermine the patent position and provoke wider generic entry prior to that date, as generic companies always wanted to be first to market.

[35] Including a settlement involving a 'reverse payment' where that can legitimately be explained on a basis other than as consideration for delay in independent market entry, e.g. on the basis of the avoided costs and disruption of litigation: Decision, paras 6.111-6.112.

> That is how it would have been interpreted in the commercial world, in my view….
>
> The entry of the first generic would provoke further attempts by generics with infringing products to enter 'at risk' and jeopardise GSK's chances of obtaining interim injunction….
>
> If we had agreed a royalty-based deal in these settlements the way it would have looked in the market place in my view is that we had allowed an infringing product onto the market – particularly with a small royalty which it has been explained to me was contemplated internally by each of GUK and Alpharma. It would have been perceived in the market as GSK lacking the determination to defend its patents, in exactly the same way, and with the same risks in terms of provoking wider generic entry, as I indicated for an early independent entry … above. We would never have done it."

260. When questioned about a royalty based licence, Dr Reilly added that:

> "… it does indicate if you allow anything onto the market that there is a reason for doing that, and the reason could be linked to the strength of your patent. Again, the discussion was we did not want to indicate that there was any weakness in the patent position, we actually were rather going to fight that in the courts."

261. However, Dr Reilly accepted that under a licence the level of royalty would be a reflection of the parties' perception of the patent strength. It therefore seems to us that the grant of a licence does not in itself indicate a lack of confidence in the patent: it would do so only if the royalties were perceived as being low. But in any event, GSK's approach at the time was adopted in an environment where it could contemplate entry into settlements in the form of the Agreements here at issue. GSK's approach might have been very different if a settlement in this form was precluded as unlawful. Any settlement of patent litigation represents a commercial judgment, informed by legal advice as to the strength of the case. Accordingly, we find it impossible to say whether an alternative form of settlement might have been practicable. We therefore cannot accept the submission that in the absence of the Agreements, GSK would necessarily – or even probably – have fought the cases to the end.

262. In our view, the difficulty presented by the CMA's approach is not that it may altogether preclude settlement of such cases, but that it may prevent a particular kind of settlement which may be the easiest to achieve in practical terms. As we understood it, the CMA's approach is not confined to cases where the patent strength, and thus the hypothetical outcome of the litigation,

is uncertain, or where it could be shown that the patent was considered to be weak so that the generic challenger would have been likely to win at trial. The same approach would apply where there was evidence demonstrating that the patent was considered to be strong. For example, where legal advice was disclosed showing that both parties believed that the patent-holder had an 80% chance of success, a settlement involving payment (in excess of avoided litigation and related costs) by the originator to the generic company would be unlawful by object since it precludes a 20% chance of independent generic entry. Mr Turner, for the CMA, did not shrink from this conclusion: indeed, he submitted that it was correct. We return to this fundamental point below.

(f) ***The supply arrangements***

263. Whatever might be the correct legal analysis of an agreement where the patentee paid a generic challenger a large sum to stay completely out of the market for a substantial period, the Appellants argued that this was clearly not the case as regards the Agreements here. Under each of the Agreements, the generic company was being allowed onto the market through the supply arrangements whereby it was being provided with a significant volume of paroxetine from GSK, either directly or through IVAX, for resale. This was referred to as "authorised generic supply". In summary, the Appellants therefore submitted that the Agreements were pro-competitive: they enabled a generic product to be introduced onto the market, with a beneficial effect on prices and NHS expenditure, whereas in the absence of the Agreements GSK might have succeeded in its patent actions and prevented any generic product coming onto the market at all.

264. Before discussing and analysing this submission in more detail, it is necessary to explain how the supply and pricing of paroxetine in the UK operated.

265. The overall demand for paroxetine is inelastic, i.e. it does not vary significantly according to changes in price. Since it is a prescription-only drug, doctors in their prescribing decisions would very rarely choose another drug instead of paroxetine based on price. Demand did experience some

decline after August 2002, but that was at least in part due to adverse publicity, including a television programme reporting significant side-effects.

266. There are well-established wholesale distribution channels for many pharmaceutical drugs. SB had largely sold its prescription drugs to such wholesalers, who in turn would resell to pharmacies. The price to wholesalers was set by reference to the manufacturer's List Price, and the general practice in the industry was to charge them List Price minus 12.5%. Following the merger of SB with GlaxoWelcome, GSK moved in January 2002 to a 'direct-to-pharmacy' model of distribution which thereby cut out the wholesalers. However, as noted above, GSK faced competition from PIs on 20mg Seroxat (there were apparently no PIs of 30mg Seroxat). PIs were sold to wholesalers, who then would compete with GSK for the custom of pharmacies, and also to pharmacies directly. The level of PI supply was somewhat volatile but it was nonetheless very significant. Prior to the Agreements enabling authorised generic supply, GSK estimated that it accounted for some 40% by volume of the UK market for 20mg Seroxat. Dr Reilly's evidence was that the PI price at the time was about £13 compared to GSK's list price of £17.76.

267. GSK responded to the competition from PIs by reaching 'brand equalisation' deals with pharmacies, which amounted to a product-specific discount paid by way of a rebate direct to the pharmacy (even before GSK introduced direct-to-pharmacy distribution) in return for a commitment to purchase only UK-originated Seroxat. The discount would be negotiated taking account of the PI price, the degree to which the pharmacy had purchased PIs and recognising that GSK could charge a premium. This was explained by Mr Sellick as follows:

> "…despite the fact that most pharmacies purchased PIs when they were available, there was a certain degree of value in all pharmacies stocking a UK product. For example, it avoided them having to deal with too many different wholesalers or varying short-line batches. It avoided pharmacies having to train staff on different packaging designs and tablet shape. It also tended to reduce the time pharmacies had to spend dealing with patient questions and complaints arising from the unfamiliar appearance of foreign packaging and tablets. SB's packaging featured writing in English rather than, as was often the case with PIs, English text on stickers concealing foreign text. We also emphasised to pharmacies the benefits of continuity of product in order to maintain consumer footfall. If a customer knew that a certain familiar branded

> drug was always available from a pharmacy, the expectation was that they would return regularly and also hopefully purchase non-prescription items whenever they were there."

268. The *average* price paid by pharmacies for 20mg paroxetine was accordingly significantly less than the GSK List Price, as a result of a combination of PI purchases and the GSK discounts. The average price paid could and did vary according to the prevalence of PIs and brand equalisation deals without involving any change in the list price for Seroxat.

269. Pharmacies were reimbursed for their purchases of prescription drugs by the NHS according to the NHS Drug Tariff (the "Drug Tariff"). The way this regime operated at the time was explained by Mr Horridge. The Drug Tariff comprised various categories and each drug was placed in a particular category. 20mg paroxetine had been in Category C, which comprised drugs which were not readily available in generic form. When a drug was considered to be readily available in generic form, it was moved to Category A. Here, 20 mg paroxetine was moved to Category A on 1 June 2002. For Category C drugs, pharmacies were reimbursed according to the originator's List Price (subject to "clawback", as explained below). For Category A drugs, the reimbursement was calculated as a weighted average of the price lists of the two national full-line wholesalers (AAH and Unichem) and three major generic suppliers. This Category A price was adjusted monthly, with the objective that as generic competition drove down the price of the drug, the Drug Tariff reimbursement price would track those changes.

270. Although the principle of NHS pharmacy purchasing was that pharmacies should be reimbursed as closely as possible to the price they actually paid for drugs they dispensed, in practice it was recognised that there was a gap between the prices they paid and the Drug Tariff prices at which they were reimbursed. Mr Horridge explained:

> "This was because:
>
> a. the actual prices paid by a [pharmacy] varied over time and depended significantly on the availability and prices of parallel imports and/or generic supplies, as well as the level of discounts and rebates provided by wholesalers or (in the case of pharmacists supplied on a 'direct to pharmacy' basis) by the manufacturer.

b. By contrast, the NHS Drug Tariff was set on a monthly basis and was the same for all [pharmacies] and all quantities. For Category C drugs it did not take into account any discounts off List Price that individual [pharmacies] were able to negotiate, or the price of parallel imports. For Category A,…the Drug Tariff price was set with reference to the list price of a basket of two wholesalers and three generic suppliers.

Because the reimbursement value was usually (although not always) higher than the aggregated [pharmacies'] purchase prices, this led to a 'retained profit' for [pharmacies]. It appeared to those of us outside the [Department of Health] that this was tolerated to a degree because it incentivised [pharmacies] to negotiate better prices with pharmaceutical companies with the objective that they could keep some of this gain for themselves. From time to time, there was a Discount Inquiry to seek to 'claw back' as much of this excess profit as possible for the NHS. However, in my experience it was well understood that pharmacists were typically 'one step ahead' and would always find a way to retain some profit."

271. The only relevant "Discount Inquiry" over this period was conducted in 2000 with respect to England and Wales. Such an inquiry was a complex exercise, seeking to determine the weighted average of the discounts which the pharmacies had in fact achieved as against purchasing dispensed drugs at full Drug Tariff prices. The result in this case was the implementation in December 2001 of a clawback rate of 11.28%[36] which was backdated to October 2000.

272. When IVAX and then GUK entered the UK market with their 'authorised supply' of 20 mg paroxetine, following their respective Agreements with GSK, they priced it at around the prevailing PI price. That was indeed what all the parties had expected, as is clear from Dr Reilly's witness statement in the GUK litigation. The PI price proved to be largely inelastic: i.e. the parallel importers did not respond with price cuts to compete with the new generic supply. Although at first sight this may seem surprising, it was common ground between the parties, and indeed their expectation at the time.[37] Thus the GSK-sourced generic supply rapidly came to displace the PI supply: PIs fell significantly on the entry of IVAX into the market in December 2001

[36] This was the overall rate: the actual clawback rate applied to an individual pharmacy varied according to a Clawback Discount Scale related to its level of purchases.

[37] Once generic products become available, PI suppliers expect prices to fall significantly and they therefore leave the market. Although because of the limited volume available under the Agreements that did not happen here in the usual way, the Agreements were confidential and, as a PI supplier explained to the CMA, "importers would be wary of importing stock in case the market price fell below their cost and left them facing losses."

following the IVAX Agreement, and declined to a minimal level following further volumes supplied by GUK following the GUK Agreement in mid-March 2002. These developments are illustrated by the graph set out at para 56 above.

273. The authorised supply pursuant to the Agreements clearly had the effect of introducing significant volumes of generic paroxetine onto the UK market. That in turn largely displaced the PIs, as expected, and also led to a significant reduction in the volume of Seroxat being sold. In October 2001, the market share of 20 mg paroxetine accounted for by Seroxat was 70-71%; by November 2003, it had declined to little over 40%. Over the same period, the market share of PIs also fell by about 30 percentage points, from about 30% to one or two per cent. The result of this change in the proportions supplied was to reduce the *average* price paid by pharmacies for 20mg paroxetine. We discuss the extent of this reduction below.

274. The contention that the Agreements had a pro-competitive effect was put in different ways by different Appellants. In summary, the arguments were directed at:

(i) An effect on the NHS. This was the principal contention of Dr Stillman in his expert evidence put forward by GSK. In his opinion, the change in categorisation under the Drug Tariff brought very substantial saving to the NHS by way of a reduction in the total reimbursement paid to pharmacies.

(ii) An effect on wholesalers. This was the principal contention of Dr Majumdar in his expert evidence put forward by GUK. Wholesalers previously could obtain only PIs whereas through the authorised generic supply there was an increase in competition for their business and between them.

(iii) A pass-through of lower prices to pharmacies.

(iv) Additional competitive pressure on GSK through loss of volume.

We address each of these contentions in turn.

(i) *Effect on the NHS*

275. Since paroxetine was a prescription-only drug, the effective payment on behalf of patients was made by the NHS through the reimbursement scheme operated under the Drug Tariff. The experts agreed that as a matter of economics the patients and the NHS can both be regarded as the final consumers, and the price paid by the NHS was effectively the consumer price. We agree with this. The introduction of authorised generic supply led to 20 mg paroxetine being moved from Category C to Category A with effect from 1 June 2002. That led to an immediate fall in the Drug Tariff reimbursement price of 12%. There was then a further fall of 3% to the price within Category A over the period June-November 2002. The adjusted figure for the aggregate reduction in NHS reimbursement is about £13.8 million.[38] This was undoubtedly a significant saving for the consumer. Dr Stillman, in particular, contended that this meant that the Agreements taken as a whole produced clear benefits for consumer welfare, which in his view showed that economic effect of the Agreements was positive.

276. However, in the first place, as Dr Stillman recognised, the availability of generic supply which led to the reclassification into Category A at the end of May 2002 was the consequence of the IVAX Agreement, which introduced significant generic supplies from December 2001. Neither the GUK Agreement nor the Alpharma Agreement therefore caused this reclassification. For GSK, it was pointed out that the CMA takes objection also to the IVAX Agreement in the Decision under Chapter II. But while this may be relevant in the context of the Chapter II case, in our view it is not relevant to the issue we are here considering: i.e. whether either the GUK Agreement or the Alpharma Agreement is to be regarded as having the object of restricting competition. The question of object is to be determined at the time an agreement is entered

[38] Dr Stillman in his report calculated the saving to November 2003 at £15.6 million, but as GSK subsequently recognised, that figure failed to take account of the 'clawback' applied following the Discount Inquiry: paras 270-271 above.

into, and by the time when each of these agreements was concluded the event triggering the 12% fall in the Drug Tariff price had already taken place. As regards the further fall of c. 3%, we heard no separate argument on that point, which is obviously much less significant, and it is not clear how that fall came about since it was not suggested that IVAX, GUK and Alpharma competed on price.

277. Secondly, the large benefit which the NHS obtained is not reflective of a fall in the average price of paroxetine charged to pharmacies but was due to the fact that the primary basis of reimbursement in Category C is the Seroxat List Price, although pharmacies in practice paid on average significantly lower prices due to PIs and brand equalisation deals. What the reclassification to Category A achieved was to reduce the retained profit enjoyed by the pharmacies. Even if the generic companies had sold paroxetine at absolutely identical prices to PIs, the effect would have been the same since it was the entry of significant generic product and not a lowering of the price which triggered the reclassification under the Drug Tariff.

278. Accordingly, this saving to the NHS was the result of the operation of the Drug Tariff regime. This regime can be seen as an imperfect attempt to capture some of the effects of competitive markets, by recognising that once generic companies have entered the market the prices at which pharmacists need to be reimbursed fall sharply. The reclassification of paroxetine from Category C to Category A therefore led to a reallocation of monies as between pharmacies and the NHS, to the significant benefit of consumers, despite the fact that the new generic supplies were limited in volume and sold at similar prices to PIs of the same drug. In the light of the way the reimbursement system operated at the time, we are not surprised that it was subject to criticism and proposals for reform: see *Options for the Future Supply and Reimbursement of Generic Medicines for the NHS, A Discussion Paper* (July 2001), which found, in summary, that "Reimbursement prices often differ significantly from true market prices."

279. We recognise that there was accordingly a public or consumer benefit resulting from the way the NHS reimbursement regime was structured.

However, the reclassification of paroxetine under the Drug Tariff, which led to this benefit, was caused by the IVAX Agreement and did not result from the subsequent GUK and Alpharma Agreements. We also note that there is no suggestion in the evidence that this reduction in price paid by the NHS formed any part of the intention of the parties when entering into any of the Agreements or was even considered at the time, although obviously all the companies involved would have been very familiar with the operation of the Drug Tariff regime.

280. Even if this benefit were directly attributable to the GUK and Alpharma Agreements we doubt that it would alter the assessment of whether they constituted a restriction by object. In our view, it would properly fall for consideration in the context of the criteria for exemption under sect 9 CA and the corresponding Art 101(3) TFEU.

281. Accordingly, we have not found it necessary to consider and assess Dr Stillman's analysis which sought to show that the benefit to the NHS was greater under the Agreements than if GSK had concluded settlements on the basis of early entry with an independent generic product.

(ii) *Effect on wholesalers*

282. The wholesalers were the main direct customers of the PI suppliers and then also of the generic entrants under the Agreements (i.e., IVAX, GUK and Alpharma). GUK, in particular, on the basis of the expert evidence of Dr Majumdar, argued that the effect on wholesalers should be seen as a critical factor in the competitive analysis of the Agreements.

283. We were told that the wholesalers operated in a competitive market, and by reason of the Agreements they were able to obtain generic paroxetine whereas previously, after GSK moved to "direct to pharmacy" distribution at the start of 2002 and thereby cut out the wholesalers, they could only obtain PIs. Thus the Agreements provided the wholesalers with an additional source of supply. The supply from the generic companies competed with the PIs on price and to some extent on quality in that generic paroxetine was regarded as preferable

compared to over-stickered foreign packaged paroxetine and generic supplies were more reliable. The figures used by the CMA for the Decision suggests that the price to wholesalers ("PTW") of generic paroxetine was some 14-16% below the price of PIs, and Dr Majumdar adopted that figure in his report. However, the PTW of PIs was essentially inferred from the price charged by the wholesalers to the pharmacies ("PTP") and Ms Webster considered that this was overstated in the CMA's calculations (and the CMA indeed recognised that this was likely due to inadequate data[39]). In her opinion the adjusted figures showed that the generic PTW was 10-12% below the PI PTW. We do not consider that it is necessary to decide between these alternative estimates.

284. There is no evidence to suggest that the three generic companies competed with each other as regards the supply of generic paroxetine. That seems clear from the fact that although IVAX, GUK and Alpharma entered the market sequentially, each introducing a further quantity of generic paroxetine, it is common ground that the PTP of such generic paroxetine did not materially change as the additional generic supplier entered the market, i.e. over the period November 2001-November 2003. Moreover, as noted above, the introduction of generic paroxetine came to displace PIs, such that by the time of the Alpharma Agreement PIs had shrunk to insignificant levels. Dr Stillman agreed with Prof Shapiro that once the PIs had been displaced by the generic product, there was then no active competition with PIs, although they remained as potential competitors "in the wings", able to re-enter the market if conditions changed.

285. However, GUK's main point was that to the extent that the lower PTW was not passed on by the wholesalers to the pharmacies, the Agreements self-evidently brought a financial benefit to wholesalers. (The experts agreed that estimating the extent of such pass-on depended on the making of assumptions.) On that basis, GUK argued that the Agreements brought about a reduction in prices to direct customers which, when contrasted with the

[39] Decision, fn 616.

uncertain benefits of continued litigation, preclude the conclusion that the Agreements had an anti-competitive object.

286. In his oral evidence, Prof Shapiro said that he did not regard any such increase in benefits to the wholesalers in the circumstances here as constituting a meaningful increase in competition. The wholesalers were essentially distributors between the supplier and the end customer of the product (i.e. the pharmacies). Prof Shapiro explained the position as follows:

> "The key thing in terms of economics is to look at what I call the locus of competition, where the firms end up competing.
>
> Let me give [an] example to illustrate. Suppose you had crude oil producers who sell their oil to refineries, who make refined products such as gasoline and that is the competition but they sell it through logistics firms who take the oil, put it on tankers, negotiate arrangements, and sell to the refineries. They have an intermediary.
>
> Suppose the crude oil producers all get together, form a cartel, and they raise the price. Suppose I told you that the logistics firms, by standard industry practice, they charge 1% of the delivered price of the crude oil as their fee for what they do.
>
> The crude oil price now doubles, the logistics firms, they have a 1% fee. So they are getting 1% on double the price. Let us suppose their costs do not change at all; they are still doing the same with the tankers and whatever, the people trading. They are delighted. The refineries are obviously the ones who are going to pay the price, the doubled crude oil price. To look at the effect on the logistics firm and say, they made more money, would be a very poor way to evaluate the effects of the cartel, even though technically, assuming they are taking title to the oil, they would be the direct customers.
>
> The point is the oil companies, the way they compete is to sell to the refineries, and that is where you want to look, not at some intermediary. The intermediary who gets a fixed cut of the price, they have a common interest with the cartel in the price being higher. So while they are direct customers, it would make no sense to look at them in that case."

287. Here, we think it is not altogether clear why the generic PTW was so much below the PTW of the PIs. But there was evidence of industry practice in determining prices by working back from the price to pharmacies, and applying a standard discount to determine the price to wholesalers. Thus Mr Sellick said that for branded drugs, when GSK sold to wholesalers it charged them its List Price less a standard discount of 12.5%. Mr Sellick said that GSK believed that the wholesalers sold to pharmacies at around 10% off List Price, and there was indeed evidence that the general practice was for

wholesalers to sell at 9-11% off the reimbursement price, leaving them a mark-up of 1.5%-3.5% of the final price. The general industry practice for PIs was that parallel importers would offer wholesalers a discount in the region of 14% and that they would sell to pharmacists at 9-11% off the reimbursement price. Thus their mark up on PI product was 3-5%. Mr Collier gave evidence that Alpharma's sales to wholesalers of generic product were generally made at a 20% discount off the pharmacy price (sometimes referred to as the "wholesaler distribution fee"). All these discounts applied across the whole portfolio of products being supplied.

288. It was common ground that if the PTP of the generic companies was about the same price as the PTP of PIs then the pharmacies would for the most part switch to purchasing the generic product. We therefore think the lower prices paid by wholesalers for the generic paroxetine compared with PIs most probably reflected the standard approach to price-setting in this industry, whereby the discount or distribution fee was a higher percentage for generic product than for PIs, presumably because once there is full generic entry prices generally fall dramatically. Although here the situation with only limited generic entry was unusual, pricing discounts offered by wholesalers to pharmacies generally applied across the whole portfolio of drugs supplied and so as regards paroxetine wholesalers got the benefit of the application of the standard approach: in effect, a windfall.

289. Dr Majumdar accepted that this appeared to be the case for Alpharma, and acknowledged that the position as regards IVAX was unclear, but relied on a written answer by GUK furnished to the CMA to support his view that GUK negotiated separately with wholesalers on paroxetine and that as regards supplies from GUK the lower price (compared to PIs) was the result of competitive negotiation. But without doubting the accuracy of what GUK said, we find its answer to be a slender basis on which to build such a conclusion. While Mr Collier acknowledged that he did not know what GUK's pricing approach would have been, we note his unchallenged evidence that Alpharma never intended to sell paroxetine at prices which much differed from the prices charged by IVAX and GUK, and that Alpharma "had no reason to cut prices to sell our limited volumes of paroxetine." There is

nothing in the contemporary documents surrounding the negotiation of the Agreements showing the companies' evaluation of GSK's offer of a limited volume of supply to suggest that they contemplated facing competitive pressure on the price they could charge when selling such volumes to wholesalers.

290. As GUK sought to mount a case that wholesalers were financially better off through achieving higher margin by reason of greater competition, we would have expected GUK to adduce much clearer evidence. Although advanced forcefully on GUK's appeal, this point was mentioned only elliptically in the lengthy administrative proceedings preceding the Decision. Not only did GUK call no evidence as to its pricing practices, it also did not adduce evidence from any wholesaler, and presented this argument on the basis of a report from its economic expert served with its Reply. While the burden of proof of infringement of course rests on the CMA, which had concluded that there was no competitive benefit from the Agreements, in the circumstances the evidential burden rests on the Appellants in seeking to establish that a competitive benefit resulted.

291. Accordingly, in our view, the fact that, depending on the rate of pass-through to pharmacies, the wholesalers received supplies more cheaply and so earned higher margins therefore does not indicate a significant competitive benefit from the Agreements. As Prof Shapiro graphically expressed it: "It took a little bit away from the pie that was available to GSK and the generics because the wholesalers got a cut there." None of this detracts from the fact that the switch of well over 50% of the total market for paroxetine in two years, from November 2001 to November 2003, to the generic suppliers from GSK and PIs constituted a massive change in the market.

292. However, there is a rather different respect in which we think the Agreements did bring some competitive benefit to consumers, and that was in terms of quality. The generic supply had the effect of displacing PIs which were less favoured by patients and pharmacies for reasons we have briefly indicated. That was the result of competition between the generic and PI supply, at least by reason of the IVAX and GUK Agreements (by the time the Alpharma

Agreement was concluded, PIs had largely disappeared). Although not the main focus of GUK's argument, it was nonetheless relied on, and Dr Stillman made this point also. We accept that after the Alpharma Agreement, since the total volume of generic supply then materially exceeded the prior volume of PIs and so took volume away from Seroxat, that led to a slight decline in quality since the branded Seroxat was the most favoured product. But we think on the evidence the net balance was a modest improvement in quality overall. In our view, this was an aspect which should have been taken into account in the Decision. Whether it materially affects the overall conclusion is another question, to which we return below.

(iii) *Effect on pharmacies*

293. As we have just observed, it is unclear to what extent the reduction in the average PTW was passed through by the wholesalers to the pharmacies over the relevant period. That depends on the wholesaler mark-up. Ms Webster, Dr Majumdar and Dr Stillman were strongly divided on what mark-up to apply, although there was some measure of consensus that at least some of the mark-ups used in the Decision appear to be inaccurate. However, all the experts were to some extent making assumptions based on incomplete data. What is clear is that the PTP of the authorised generic product was significantly below that of Seroxat. Further, just as the generic companies were not competing with each other in the sale to wholesalers, we do not see that wholesalers would have been competing as regards their sales of generic product to pharmacies. The Agreements led to the supply of limited quantities of generic paroxetine which in aggregate was significantly less than total market demand; and that demand was inelastic. Therefore the wholesalers, like the generic companies, knew they could sell all the generic paroxetine they obtained and there was no incentive for them to compete on price.

294. Significantly, there was a reduction in the overall weighted *average* price of 20 mg paroxetine supplied to pharmacies due to a change in the mix. Altogether the three generic entrants took an extra 30% of volume share of 20mg paroxetine from GSK over the prior PIs over the period from IVAX's entry in November 2001 to independent generic entry in November 2003: see

the graph at para 56 above.[40] Hence the volumes of authorised generic supply pursuant to the Agreements meant that pharmacists reduced the share of their purchases accounted for by higher priced Seroxat. The extent of this reduction compared to the period prior to the Agreements is difficult to estimate with accuracy, in particular because of problems with the data concerning (i) GSK's prices in 2001 before it moved to direct-to-pharmacy distribution; (ii) the wholesale mark-ups to be applied to the prices charged by IVAX, GUK and Alpharma; and (iii) according to Ms Webster, the probable overstatement in the Decision of the prices charged to pharmacies for PIs. There is a yet further complication in attributing the estimated reduction entirely to the authorised generic supply pursuant to the Agreements, since there was a significant decline in the demand for paroxetine from August 2002 due to adverse publicity (see para 265 above). That has two implications: (a) in the absence of authorised generic supply, if the volume of PIs had remained the same, the market share accounted for by Seroxat would have declined in any event, causing a decline in the average price; and (b) to the extent that the volume of authorised generic supply exceeded the previous volume of PIs, the effect of the market contraction was to cause a greater decline in the average price than would have occurred in the absence of such generic supply.

295. Without making adjustment for market contraction, Dr Stillman estimated the decline in the weighted average price as between 3.5% and 4.3%, Dr Majumdar's estimate was 3-4%, and Ms Webster's estimate was between 2.7% and 3.4%. The differences between Dr Stillman and Ms Webster are accounted for by their different treatment of factors (i) and (ii) above, and the mid-point between Dr Stillman's high estimate and Ms Webster's low estimate is 3.5%. Ms Webster further explained that she had not adjusted her estimates for what she considered was an overstatement of the PI prices in the Decision: if that further adjustment was made (for a 2.5% overstatement in the PI price) then her estimate for the range of likely decline in average price reduced to between 2% and 2.8%. Dr Stillman and Dr Majumdar did not

[40] Seroxat's share (by volume) fell from c. 70% in November 2001 to c. 40% in November 2003.

accept that the PI prices had been overstated and so disputed the justification for this further adjustment.

296. As regards the decline in the size of the market, we think that this probably could not have been anticipated, at least at the time of the GUK Agreement. For the purpose of assessing *ex ante* the object of the Agreements, we therefore accept that the effect of that factor should ideally be excluded when considering the GUK Agreement. Ms Webster and Dr Stillman agreed that if the actual decline in average price were adjusted for the decline in the total volume of sales that began around August 2002, the effect of that adjustment would be to reduce the estimated decline in average prices by about 0.9 to 1.0 percentage points, such that the mid-point of Dr Stillman's and Ms Webster's analysis falls to around 2.5% (without taking account of any overstatement of PI prices).

297. We do not think it is necessary to reach a view as to which of the alternative estimates of price decline is correct since, first, there is a margin of error in all the estimates and, secondly, we consider that the difference between them does not affect the outcome of these appeals. Therefore, we proceed on the basis that there was a small but not insignificant benefit by way of reduction in the average price of paroxetine to pharmacies. Further, this was a benefit at the level, to adopt Prof Shapiro's phrase, which was 'the locus of competition'.

298. However, this price reduction was the inevitable result of GSK, in effect, ceding a part of the market for 20 mg paroxetine to the three generic companies by selling them limited volumes at a price which enabled them to resell at around the PI price, and thus significantly below GSK's Seroxat price. In our judgment, this was not a normal competitive process. The resulting price reduction to pharmacies was the consequence of a significant change in the structure of the market engineered by GSK.

(iv) *Competitive pressure on GSK*

299. The experts disagreed as to whether the supply of generic paroxetine which resulted from the Agreements acted as a constraint on GSK. Dr Stillman thought it did. As he put it: "it has caused a reduction in demand [for Seroxat] which I think of as being a way of operationalising [*sic*] this phrase 'competitive constraints'." And Dr Majumdar said:

> "The way I see it is that GSK faced lower-priced rivals than absent the supply agreement[s] in the sense that the price to pharmacy of the entrants' products in my view was below the price to pharmacy of the parallel imports. That suggests to me that GSK faced greater competitive constraints than absent the supply agreement[s]."

Prof Shapiro was emphatic that there was no resulting competitive constraint.

300. In our view, the theoretical approach adopted by Dr Stillman and Dr Majumdar does not reflect the reality of this case. There is no suggestion in the evidence from GSK, in particular the witness statement of Dr Reilly, that GSK ever regarded the Agreements as likely to create downward pressure on GSK's own price. GSK was expecting to lose volume of its Seroxat product but was not expecting to compete on price with these three authorised generic suppliers and indeed GSK, by amendment of the IVAX Agreement, was underwriting the profit guarantee which GUK received on its authorised generic supply. Moreover, Mr Sellick, whose evidence covered the way GSK set prices to pharmacies, did not suggest that GSK had to offer greater "brand equalisation deals" to pharmacies as result of any of the Agreements. Dr Reilly said that in addition to achieving settlement of the patent disputes, GSK saw the Agreements as having the benefit for it of leading to the displacement of PIs and securing the production output of its dedicated factory. And since there can be no suggestion that this generic paroxetine was competing with Seroxat on quality, the only meaningful source of constraint would be on price.

301. Examination of whether there was any decline in the weighted average price paid by pharmacies for 20mg Seroxat between 2001 (i.e. before the IVAX Agreement) and November 2003 is complicated by the need to resolve problems over the GSK pricing data for 2001, which all the experts who examined it have recognised. Dr Stillman considered that any price reduction

was only in the range 0.4%-1.5%; while Ms Webster did not accept that there is any robust evidence of a price decline and found that the Seroxat price moved between -1% and +1%. Even if such decline occurred, it was minimal having regard to the quantity of generic paroxetine introduced onto the market. As Dr Stillman accepted in the 'hot tub' discussion: "there is not, I think it is quite clear, any appreciable reduction in GSK's price". And Dr Majumdar said: "it is agreed that the price of Seroxat, if it fell, was in the range of 0%-1.5% decline which is small and therefore suggests that any competitive constraint faced by GSK was small…"

302. Moreover, if it was the case that GSK faced a competitive constraint from the generic supply resulting from the Agreements, the level of that constraint would have increased with each successive Agreement. However, there is no suggestion that the introduction of a significantly greater volume of generic product following the Alpharma Agreement led to any reduction in GSK's price for 20 mg Seroxat: indeed the evidence is that the price marginally increased.

303. The reason why GSK entered into the Agreements was because of the risks caused by the challenges to its patents. Since under the Agreements the quantities supplied by GSK to the generic companies were capped and total demand was fairly inelastic, we do not accept that the Agreements can properly be regarded as giving rise to any meaningful competitive constraint on GSK. The Agreements amounted to a monopoly supplier – the patent holder - agreeing to share a significant but limited part of the market with independent distributors of its own product, which it knew they would price at below its own list prices.

304. We accordingly uphold the finding in the Decision, at para 7.41:

> "The CMA does not consider that GSK's falling share of sales volumes can be attributed to an increase in competitive pressure. The market share losses suffered by GSK were the consequence of its allocation of volumes to be Generic Companies. However,…, the transfer of a restricted volume of product to the Generic Companies could not reasonably have been expected to expose GSK to a meaningful increase in competition."

In our view, the supply to the generic companies was not intended to introduce price competition with GSK, nor did it in fact do so. All it did was to compete away the PIs and reduce the market share of Seroxat.

305. Nor did GSK face any competition at the manufacturing level. As the Decision correctly states, at para 7.44:[41]

> "GSK did not face any actual competition at the manufacturer level. GSK remained the sole manufacturer of paroxetine sold in the UK throughout the term of the Agreements and prior to independent generic entry which began in December 2003 (with a market share by value or volume of 100% at the production level)."

GSK did continue to face a limited competitive constraint from parallel importers (as indeed did the generic companies) since they were in effect 'waiting in the wings' and could have re-entered the market if prices had risen or if they became able to access cheaper supplies from other parts of the EU.

Conclusion on benefits

306. As explained above, we have accepted that the Agreements taken as a whole brought some benefits, of which the most significant are the saving to the NHS by reason of the reallocation under the Drug Tariff, a modest but not insignificant decline in the weighted average price to pharmacies due largely to a change in the mix (i.e. a lower proportion of higher priced Seroxat), and displacement of PIs by a generic product which was to some extent preferred by customers. The Appellants, and GUK in particular, seized on the following observation by Prof Shapiro in the Experts' Joint Statement:

> "When applying the pay-for-delay inference to cases where the value transfer takes a non-cash form, it may be necessary to determine whether the arrangement comprising the value transfer itself could be expected to lead to a meaningful increase in competition that would predictably benefit customers. In my view, a presumption of harm to competition is warranted in such cases, just as in the case of cash payments from the patent holder to the generic, but that presumption can be rebutted by a showing that the value

[41] Although expressed in the Decision in discussion of the GUK Agreement, since Alpharma did not advance a case of increased competitive pressure on GSK, these findings apply equally to all the Agreements.

> transfer itself is likely to enable genuine competition that will benefit customers."

307. However, Prof Shapiro explained when giving oral evidence, first, that he was there addressing a situation where the *entire* consideration is in the form of a non-cash transfer. The Agreements here all contained very substantial cash value, for which in his view there was no good explanation other than removal of the risk of independent entry by the generic company. He also made clear that he regarded the non-cash value in these Agreements as equivalent to cash: a handing over by GSK to the generic company of part of the profits to be made on sale of the limited quantities supplied. Aside from those considerations, for reasons we have explained, we do not regard the benefit to either the NHS or to pharmacies (and also the increased margin for wholesalers) as the result of genuine unrestricted competition. By contrast, the displacement of PIs by generic paroxetine was a competitive benefit. However, in our view this benefit was relatively modest and does not necessarily preclude each Agreement taken as a whole from having an anti-competitive object. Indeed, since that displacement had effectively been realised by the time of the Alpharma Agreement, a contrary conclusion would suggest that the Alpharma Agreement might have an anti-competitive object whereas the GUK Agreement did not: such a distinction in our judgment is unrealistic and inappropriate when we think that all three Agreements had the same fundamental object.

308. Equally, in our judgment, if an agreement by its nature materially distorts the structure of the market by impeding actual or potential competition, the fact that the distorted structure brings certain advantages or benefits, including some limited competitive benefit, does not preclude a finding that the agreement, viewed overall, has an anti-competitive object. Any benefits which result are, in our view, then to be taken into account when considering the question of individual exemption under sect 9 CA or Art 101(3). We note that this is consistent with statement of the General Court in *Lundbeck*, at para 498:

> "The anticompetitive object of those agreements being sufficiently established – since they amount to agreements excluding potential competitors from the market in exchange for payment – even if they might

> also have benefited competition and consumers, those effects must be demonstrated by the applicants and examined in the light of Article 101(3) TFEU…and not evaluated by the Commission in the context of the first paragraph of that article…."

(g) ***The Lundbeck judgments***

309. We have conducted the analysis on 'object' with little reference to the recent *Lundbeck* judgments, which are now under appeal: see paras 85, 145-147 above. The Decision here preceded those judgments. However, the question whether patent settlement agreements involving value transfers constitute a restriction by object for the purpose of Art 101 has now to be considered in the light of the proceedings in *Lundbeck*. It is necessary therefore to discuss those complex cases in more detail.

310. As already explained, Lundbeck is a Danish pharmaceutical group which developed an anti-depressant drug containing the active ingredient citalopram. Lundbeck obtained a number of patents concerning different processes for manufacturing citalopram: see para 145 above.

311. In 2002, Lundbeck entered into six agreements with four generic companies that were threatening to market citalopram independently, as follows:

(1) Merck (GUK) - two agreements covering (a) the UK (the "GUK UK Agreement") and (b) the EEA excluding the UK (the "GUK EEA Agreement").

(2) Arrow – two agreements covering (a) the UK (the "Arrow UK Agreement") and (b) Denmark (the "Arrow Danish Agreement").

(3) Alpharma – an agreement covering the EEA, Norway and Switzerland (the "Lundbeck-Alpharma Agreement").

(4) Ranbaxy – an agreement covering the EEA (the "Ranbaxy Agreement").

312. In summary, those agreements had the following characteristics:

(1) Each agreement was for a fixed term, which initially was no more than a year, save for the Lundbeck-Alpharma Agreement which had a term of just over 15 months. Some of the agreements were extended by later amendment but all lasted less than two years.

(2) All the agreements were made in the context of an allegation by Lundbeck that the generic company was infringing or threatening to infringe one or more of the process patents (the "IP rights").

(3) Under all the agreements, the generic company agreed to deliver its stock of alleged infringing product to Lundbeck (save for the Ranbaxy Agreement wherein it is not suggested that Ranbaxy had yet shipped any stock from India to the EEA).

(4) All the agreements involved a substantial transfer of cash value from Lundbeck to the generic company. For example:

(i) Over the term of the GUK UK Agreement (as extended), Lundbeck transferred the equivalent of €19.4 million to GUK; and over the one year of the GUK EEA Agreement, Lundbeck transferred the equivalent of €12 million to GUK.

(ii) Over the 15 months of the Lundbeck-Alpharma Agreement, Lundbeck agreed to pay Alpharma US$12 million, of which US$11 million was expressed to be for Alpharma's stock of generic citalopram.

(iii) Over the 18 months of the Ranbaxy Agreement (as extended), Lundbeck agreed to pay Ranbaxy US$9.5 million.

(5) Under all the agreements, the generic company agreed as regards the relevant territory and for the term of the agreement not to manufacture, import or sell citalopram which Lundbeck alleged might infringe its IP rights.

(6) Most of the agreements stated that they were entered into because of the desire of the parties to avoid litigation. For example:

(i) the GUK UK Agreement stated that the payments by Lundbeck to GUK and the delivery of its product by GUK to Lundbeck would constitute full and final settlement of any claims that Lundbeck might have against GUK for infringement of its IP rights.

(ii) the Arrow UK Agreement recited that Lundbeck had intended to bring infringement proceedings against Arrow and threatened to seek an interim injunction; and it was a term of the agreement that Lundbeck would start such proceedings and have the obligations of Arrow incorporated in a consent order.

(iii) the Lundbeck-Alpharma Agreement included a recital stating that Lundbeck had commenced proceedings against Alpharma seeking an injunction in the UK and that Lundbeck "has agreed to compensate Alpharma in order for Lundbeck to avoid patent litigation"; and following the agreement the parties consented to an order staying those proceedings.

(7) Several of the agreements included an arrangement for the supply by Lundbeck of up to a limited volume of its citalopram for the generic company to sell in the relevant territory:

(i) Under the GUK UK Agreement, Lundbeck agreed to fulfil orders from GUK for up to 125,000 packs per month of Lundbeck's 20mg Cipramil tablets and to guarantee (through adjustment of the price) that GUK would earn £5 million net profits over the year for the full volume (or pro rata for a lesser volume); on the first extension, the profit guarantee was varied slightly to £400,000 per month; on the second extension it was increased to £750,000 per month.

(ii) Under the Ranbaxy Agreement, Lundbeck agreed to sell limited quantities of Cipramil to Ranbaxy with a discount of 40% on the ex-factory price, for Ranbaxy to sell on the UK market. The quantities were fixed as up to 10% of the volume sold by Lundbeck in the UK the previous month, and the value of the discount was estimated by the Commission at £3 million.

313. As noted above, the Commission determined that by those agreements Lundbeck and each of the respective generic companies had infringed Art 101(1) 'by object' and imposed substantial fines; and the General Court dismissed all the appeals. As well as rejecting the arguments that the generic company was not to be regarded as a potential competitor to Lundbeck (see paras 148-157 above), the General Court held that the Commission had properly found that these agreements were 'by object' infringements.

314. The CMA relied strongly on the *Lundbeck* judgments on this issue, as it had on the issue of potential competition. It submitted that those judgments determined:

(1) The fact that a certain kind of agreement had not in the past been considered to be, by its object, restrictive of competition, does not prevent a finding of restriction by object where an individual and detailed examination of the measures in question, having regard to their content, purpose and legal and economic context, reveals a sufficient degree of harm to competition; and this is not inconsistent with the judgment in *Cartes Bancaires*: *Lundbeck*, paras 343, 438.

(2) In order to find that an agreement has as its object the restriction of competition, the examination of a hypothetical counter-factual scenario is not required; such an examination is more an examination of the effects of the agreement: *Lundbeck*, para 473. The General Court continued, at para 474:

> "…even if some generic undertakings would not have entered the market during the term of the agreements at issue, as a result of infringement actions brought by Lundbeck, or because it was impossible to obtain an

> MA within a sufficiently short period, what matters is that those undertakings had real concrete possibilities of entering the market at the time the agreements at issue were concluded with Lundbeck, with the result that they exerted competitive pressure on the latter. That competitive pressure was eliminated for the term of the agreements at issue, which constituted, by itself, a restriction of competition by object, for the purpose of Article 101(1) TFEU."

(3) Where:

(i) the outcome of the patent dispute between the originator and the generic challenger wishing to enter the market was uncertain at the time of the agreement, the agreements exchanged that uncertainty for certainty that the generic company would not enter the market during the term of the agreement: *Lundbeck*, paras 363, 369; and

(ii) this was secured by means of significant 'reverse' payments which were sufficiently high to induce the generic companies to accept the limitations on their autonomy and reduce their incentives to enter the market with their own generic product: *Lundbeck*, para 414

that constitutes a restriction by object: *Lundbeck*, paras 401. Further, see at para 352:

> "…where a reverse payment is combined with an exclusion of competitors from the market or a limitation of the incentives to seek market entry, the Commission rightly took the view that it was possible to consider that such a limitation did not arise exclusively from the parties' assessments of the strength of the patents but rather was obtained by means of that payment (recital 604 of the contested decision), constituting, therefore, a buying-off of competition."

315. The Appellants sought to distinguish the *Lundbeck* judgments. We have summarised and addressed above the points of distinction relied on as regards the issue of potential competitors: see paras 150-158 above. As regards the issue of a restriction 'by object', the Appellants pointed to the following further differences which they submitted were very material, in particular:

(1) Some of the restrictions imposed under the agreements went beyond the scope of the patents;

(2) The payments made by Lundbeck to the generic companies were found to equal or exceed the profits the generic companies could have made by independent entry, whereas here the CMA gave up its attempt in the administrative proceedings to find such equivalence; and

(3) There were no supply agreements, save under the GUK UK and Ranbaxy Agreements and those were for supply of branded Cipramil not a generic product.

316. As regards point (3), Mr O'Donoghue, who made submissions regarding the *Lundbeck* judgments on behalf of all the Appellants, argued that the supply provisions under the Agreements here "were of a fundamentally different character and pro-competitive effect [compared] to the supply agreements in *Lundbeck*." In support, he pointed to passages in the Commission's decision discussing the GUK UK Agreement:

> "(799)…, reimbursement levels in the United Kingdom were linked to generic entry into the market, not to any increase in the number of suppliers of the originator product. Thus, by turning Merck (GUK) into an exclusive supplier of its own product, Lundbeck avoided any impact on the United Kingdom reimbursement level for citalopram, which Merck (GUK)'s (and Arrow's) entry as a supplier of generic product would have had. This guaranteed Lundbeck continued high profits on its sales of citalopram. Consumer interests were hurt, however, in that significant price decreases for citalopram that in all likelihood would have resulted from generic entry were prevented for the duration of the agreement.
>
> (800) For the reasons mentioned in recitals (798) and (799), the agreement with Lundbeck also cannot be seen as a pro-competitive supply agreement that allowed Merck (GUK) early market entry or substantially facilitated later market entry. Firstly, by distributing citalopram that was Lundbeck branded, Merck (GUK) became dependent on Lundbeck and could not build up any brand recognition as (generic) supplier of citalopram. Secondly, Merck (GUK) was getting ready, at the time when it concluded the agreement with Lundbeck, to enter the United Kingdom market with its own generic product."

317. In response, Mr Turner pointed to the second reason there relied on by the Commission, which went on to state that the positive impact from independent generic entry would have been much greater than under the supply

arrangement.[42] Moreover, he relied on the General Court's view of the Ranbaxy Agreement and the ground on which the Court rejected the contention that the supply arrangement meant that the agreement had a pro-competitive character that precluded it from being a 'by object' restriction: *Ranbaxy*, paras 248-249:

> "…The provisions concerning distribution were an integral part of the agreement at issue and served to supplement the consideration granted to the applicants for refraining from the production and sale of their own citalopram during the relevant period…
>
> Moreover, it is immaterial whether discounts are common in the pharmaceutical sector, given that the discount at issue was not granted under normal conditions of competition. In addition, the applicants do not explain the reason, other than as consideration for the obligations set out in Article 1.1,[43] that Lundbeck granted them 10% of its Cipramil sales in the United Kingdom, at a price 40% less than Lundbeck's ex-factory price, which constituted a loss of GBP 3 million for Lundbeck."

318. The Appellants appear to be correct in asserting that the supply arrangements considered in *Lundbeck* were not considered to have brought any benefits for customers, whether direct or indirect, and so appear to be distinguishable from the supply arrangements here. Moreover, points (1)-(2) above were all relied on, to greater or lesser extent, by the General Court. However: (a) those points did not apply as regards all the agreements condemned in *Lundbeck*; and (b) it is unclear in any event whether those circumstances, as set out in the various passages in the *Lundbeck* judgments to which the Appellants referred, were simply additional factors which supported the fundamental reasoning or material differences which might point to a different conclusion in the present case. While there are undoubtedly differences on this issue, as on the issue of potential competition, it seems to us that there are also some close parallels between *Lundbeck* and the circumstances of the present cases.

319. By reason of sect 60 CA, the Tribunal is bound by the interpretation of the concept of restriction by object applied by the European Courts, including the General Court. We do not accept the submission of Mr Flynn that if we disagreed with the judgments of the General Court (e.g. if we consider them

[42] See also recital 798 of the Commission's decision.
[43] i.e. the restriction on independent generic entry by Ranbaxy.

out of line with *Cartes Bancaires*) we would be free to depart from them because they are under appeal. There is no question in that regard of the *Lundbeck* judgments being *per incuriam*: they expressly refer to *Cartes Bancaires* and seek to apply it. In any event, as we have explained above, we do not consider that *Cartes Bancaires* is determinative of the issue before us. But the fact that the *Lundbeck* judgments are all under appeal means that the approach which they adopt may be clarified or reversed by the CJEU, in a judgment which would become binding on the Tribunal and the English courts.

(h) *Conclusion on 'object'*

320. We have summarised, with inevitable omission of much of the detail, the arguments of the parties on the various alleged benefits and expressed our view on whether and to what extent those are properly to be regarded as pro-competitive consequences. But we consider that those matters are of limited significance compared to the much more fundamental question raised by these appeals. There can be no doubt that the various potential benefits that we have discussed are dwarfed by the effect that would flow from independent and unrestricted generic entry ("genericisation"), as indeed occurred from December 2003:

(1) Genericisation brought a much greater fall in the price of 20mg paroxetine than resulted from the Agreements: as noted above, prices fell by 34% in the first three months, by 52% in the first six months and by 69% by one year later (representing a fall from £12.95 to £3.97 per pack).[44]

(2) None of the alleged benefits related to 30mg paroxetine. Although the 30 mg dose was prescribed much less than the 20mg dose, 30mg Seroxat commanded a higher price (presumably in part due to the absence of PIs) and was far from insignificant. It accounted for about

[44] Decision, para 3.387.

27% of NHS expenditure on paroxetine in 2001-02, and was proportionately much more profitable for GSK.[45]

321. We therefore consider that the fundamental question is this: when the strength[46] of a patent is uncertain, does a transfer of value from the originator to the generic company in an amount substantially greater than avoided litigation costs and which cannot be explained on the basis of payment for any goods or services to the patent holder, under a settlement agreement whereby the generic company agrees not to enter the market with its generic product and not to challenge the originator's patent for the duration of the agreement (which is no longer than the unexpired period of the patent), constitute a restriction 'by object'? In that regard, we emphasise that:

(1) The uncertainty as to patent strength means that whereas there is a not insignificant chance that had the patent case gone to trial, the generic challenger would have succeeded, provoking genericisation of the whole market and a sharp fall in prices, equally there is a not insignificant chance that the originator would have succeeded, preventing that generic company from entering the market in any event.

(2) The Tribunal (or court assessing the competition law question) cannot be expected to conduct a mini-trial as to patent strength, or reach a view on that question without the disclosure of legally privileged advice. In *FTC v Actavis, Inc*, 133 S Ct 2223 (2013), where the US Supreme Court addressed some of these issues, the majority judgment suggested (at 2236-37) that: "the size of the unexplained reverse payment can provide a workable surrogate for a patent's weakness, all without forcing a court to conduct a detailed exploration of the validity

[45] Tables 4.2 and 4.3 of the Decision gave figures for GSK's sales and profits on 20 mg and 30 mg Seroxat for the years 2001-2005. Although it was accepted by the CMA during the hearing that the Tables need some correction, and the extent of adjustment was not agreed as between the CMA and GSK, it was not in dispute that GSK's profit margin on 30mg was significantly higher than on 20mg paroxetine.

[46] i.e. whether the patent is valid and whether the generic company's product infringes: see para 194 above.

of the patent itself." However, here the Decision did not suggest that an inference as to patent strength (or weakness) could be drawn from the size of the value transfers, and the Appellants' experts explained why that would be inappropriate having regard to such issues as risk aversion and asymmetry of information.

(3) In our view, an outcome of the litigation whereby the patent was upheld and the generic company found to infringe is not to be regarded as less competitive than an outcome the other way, since the purpose of the patent system is to stimulate innovation, which promotes dynamic competition. A court determination that a patent is valid and infringed therefore cannot properly be regarded as a "negative" result for consumers even if it means that they will continue to pay higher prices for the patented goods. Such determinations are a necessary means of ensuring that patent-holders receive the proper rewards for their innovations.

322. This fundamental question brings into focus the so-called "pay-for-delay inference" espoused by Prof Shapiro (among others) and which is reflected in the Decision. In the experts' joint statement, this was expressed in high-level terms as follows:

> "…patent settlements with value transfers [significantly in excess of avoided litigation costs] from the patent holder to the potential generic entrant in exchange for an entry restriction are likely to harm competition and reduce consumer welfare relative to the welfare that consumers could expect from either continued litigation or from an alternative settlement without a value transfer."

323. However, the rationale for the inference is that such a transfer of value amounts to a sharing of monopoly profits as between the originator and the generic company instead of that financial value applying to benefit consumers.[47] It seems to us that application of the pay-for-delay inference necessarily involves consideration of what might have happened in the

[47] See also *Lundbeck* at para 429: "… the parties to the agreements at issue were able to share a part of the profits that Lundbeck continued to enjoy, to the detriment of consumers who continued to pay higher prices than those they would have paid if the generic companies had entered the market…"

absence of the impugned agreement (see para 314(2) above). The alternatives suggested were (a) ongoing litigation to judgment, or (b) an alternative settlement that did not involve a value transfer by GSK. As to (a), that would have preserved the chance of either party succeeding. As to (b), that would have been a settlement where the parties' perceptions of patent strength and attitude to risk were more closely reflected in the degree of generic entry permitted: i.e. the level of royalty if the settlement was by a licence or the date of permitted early entry if the settlement was an early entry agreement.

324. Although we heard much argument at the theoretical level regarding the pay-for-delay inference, in particular as between Prof Shapiro and Dr Jenkins, who strongly challenged it as failing properly to take account of asymmetry of information, risk aversion and inefficient bargaining, and it has been extensively discussed in academic literature, the question for us is whether there is a 'by object' restriction on the facts of the present cases. In that regard:

(1) We think that parties to a patent settlement will often have differing views of patent strength and different attitudes to risk. But empirical evidence from the US shows that after the Federal Trade Commission started to challenge patent settlements involving reverse payments, although settlements of that type dramatically declined, the overall level of patent settlements was not affected: Decision, para 6.25.[48]

(2) We have found that the substantial value transfers were an important part of the reasons why GUK and Alpharma decided to accept the restrictions on their planned independent entry into the market. The fact that a large value transfer may have facilitated settlement on those terms does not mean that settlements with a more competitive outcome were unlikely in the present cases. Indeed, on the basis that the supply

[48] The Decision also records the finding in the Commission's Report on its pharmaceutical sector inquiry (para 57 above) that over 78% of patent settlements either included no restriction on generic entry or some restrictions with no value transfer from originator to the generic company: para 6.24. However, we think such overall figures are less relevant since patent settlements can occur in a wide variety of circumstances.

of limited volumes of paroxetine by GSK to the generic companies under the Agreements was pro-competitive (which the CMA disputes), Dr Jenkins accepted in cross-examination that the supply of greater volumes instead of the cash payments under the Agreements would have been more competitive. She said that the relevant question was therefore whether such a settlement was possible in the present case. However, the original Alpharma Agreement provided at cl 6 for potential supply of other products to ensure a transfer of value of £500,000, whereas in the Amendment to the Alpharma Agreement a year later there was substituted for cl 6 the supply of a further 620,000 packs of 20mg paroxetine. At least as regards Alpharma, that shows that it was likely that settlement could have been reached with a lower cash sum and a greater volume of supply, and we have no reason to think that GUK would have taken a different commercial approach.

(3) Since GSK suggested that it was risk averse, we consider it is impossible to determine whether GSK would in fact have entered into such an alternative form of settlement which did not involve a value transfer by GSK if it was not permitted to conclude agreements of the present kind: para 261 above.

(4) Even if there were grounds for overturning the view in the Decision that alternative forms of settlement were possible, that takes one back to the other alternative of continuing litigation and the question whether a large value transfer to secure agreements of the kind at issue here is anti-competitive.

325. These appeals raise a second question, which may be summarised as follows: if a patent settlement agreement involving a substantial value transfer in return for the exclusion of independent entry should be held to have an anti-competitive object, is the position different as regards an agreement which provides for more limited, but nonetheless certain, benefits for consumers through the supply of limited volumes of authorised generic product; or is such a case to be assessed only under the criterion for exemption set out in sect 9 CA (corresponding to Art 101(3))? In that regard, we note that:

(1) The supplies of limited volumes of GSK-manufactured paroxetine to GUK and Alpharma should be regarded as non-cash value transfers.

(2) The saving to the NHS was significant but resulted from the particular way in which the public reimbursement mechanism for prescription drugs was structured, and in any event was directly attributable to the earliest of the three Agreements and not to the two subsequent Agreements which are alleged to have infringed the Chapter I prohibition.

(3) The financial benefits provided to wholesalers and pharmacies should not be regarded as resulting from genuine competition, nor did the Agreements bring any increased competitive constraint on GSK.

(4) The substitution of generic paroxetine for PIs involved a modest improvement in quality resulting from increased competition.

(5) The entry into settlements involving a limited supply of generic paroxetine was a conscious strategy by GSK, as shown by its internal documents, to avoid the risk of a successful challenge to its paroxetine patents: para 227 above.

326. We consider that the two questions we have set out in paras 321 and 325 are of wide importance, and it cannot be suggested that the answers are *actes clairs*. We have indicated in this judgment our views on, in particular, the second question (see para 308 above). Nonetheless, in light of the pending appeals against the *Lundbeck* judgments, we consider it is appropriate to refer both these questions to the CJEU. Moreover, it is appropriate to include in the reference the question of the relevance of some of the suggested points of distinction with *Lundbeck* urged by the Appellants.

(3) Did the GUK and Alpharma Agreements have an anti-competitive effect?

327. All the Appellants challenged the finding that the relevant Agreement was a restriction 'by effect'. This was Ground 4 of GSK's appeal; Ground 3 of GUK's appeal; Ground 2 of Merck's appeal; Ground 2 of Actavis' appeal; and Ground 2 of Xellia/ALLC's appeal.

328. As the expression suggests, a finding that an agreement gives rise to a restriction by effect requires consideration of whether the agreement was in fact likely to have restricted or distorted competition on the relevant market to an appreciable extent. Therefore, fundamental to an 'effects' case is the counter-factual: i.e. what would have happened in the absence of the agreement? That includes a potential effect on competition. See Case C-7/95P *John Deere Ltd v Commission* EU:C:1998:256, at paras 76-77. This was not in dispute.

329. The Appellants all emphasised what they contended were the pro-competitive effects of the GUK and Alpharma Agreements due to the supply of significant but limited quantities of generic paroxetine from GSK: the saving to the NHS; the benefits for wholesalers and the competition with PIs; and the small reduction in the average price paid by pharmacies. We have discussed each of these in the context of the 'object' case above. However, while we accept that each Agreement is to be viewed as a whole, in its economic and legal context, if it can be shown that the counter-factual was appreciably more competitive than limited competitive benefits that may have resulted from the Agreement, we do not consider that those benefits preclude a finding of infringement by effect.

330. However, in order to show a restriction by effect, in our judgment it is necessary to establish it on the balance of probabilities: i.e. that it is more likely than not that the counter-factual would have been more competitive. Hence the Commission's Guidelines on horizontal cooperation agreements, (2011) OJ C11/1, state at paras 28-29:

> "28. Restrictive effects on competition within the relevant market are likely to occur where it can be expected with a reasonable degree of probability

> that, due to the agreement, the parties would be able to profitably raise prices or reduce output, product quality, product variety or innovation. This will depend on several factors such as the nature and content of the agreement, the extent to which the parties individually or jointly have or obtain some degree of market power, and the extent to which the agreement contributes to the creation, maintenance or strengthening of that market power or allows the parties to exploit such market power.
>
> 29. The assessment of whether a horizontal co-operation agreement has restrictive effects on competition within the meaning of Article 101(1) must be made in comparison to the actual legal and economic context in which competition would occur in the absence of the agreement with all its alleged restrictions (that is to say, in the absence of the agreement as its stands (if already implemented) or as envisaged (if not yet implemented) at the time of assessment). Hence, in order to prove actual or potential restrictive effects on competition, it is necessary to take into account competition between the parties and competition from third parties, in particular actual or potential competition that would have existed in the absence of the agreement. This comparison does not take into account any potential efficiency gains generated by the agreement as these will only be assessed under Article 101(3)."

331. We did not understand any of the Appellants to challenge this approach, while emphasising that the burden of proof rested on the CMA. The Decision summarises the finding of restriction 'by effect' at para 7.3:

> "In the absence of the Infringing Agreements, it is likely that the relevant litigation would have continued and the validity and infringement of GSK's patent rights would have been tested by GUK and/or Alpharma in court, or else the Parties would have entered into settlements on terms that reflected the real uncertainty that GSK faced about the strength of its patent claims. Had GUK and/or Alpharma pursued their strategy of independent entry by progressing the litigation, there would have been the real possibility of a victory for GUK and Alpharma, leading to independent, effective, generic competition. Alternatively, if the Parties had settled their differences, the agreed terms would not have involved the transfer of value by the incumbent to delay independent entry by the challengers."

That approach is developed in the subsequent paragraphs of Section 7 of the Decision. The CMA's view of the counter-factuals is further summarised as regards GUK, at para 7.47:

> "Absent the GUK-GSK Agreement, GUK would have continued to be a competitive threat and remained a potential competitor to GSK that was pursuing its efforts to enter the market independently of GSK. GUK's competitive behaviour would not have been distorted by value transfers made in return for entry restrictions. The realistic and likely outcomes are that GUK would have pursued its challenge to GSK's patent claims or, alternatively, that GUK would have entered into a settlement on terms that were not 'bought' using the value transfers, and that legitimately reflected the uncertainty regarding GSK's patent claims."

The same reasoning is applied as regards Alpharma: see at para 7.100.

332. By referring to GUK and Alpharma pursuing their challenges to the patent claims, it is not suggested that continuing litigation was in itself a competitive counter-factual. In other words, it was not a ground of the Decision or a part of the CMA's case that the process of having to defend its patents in court and/or prove infringement operated as a competitive constraint on GSK's pricing of Seroxat. As Mr Turner confirmed, the CMA is there referring to the possibility of GUK or Alpharma proceeding with the litigation to what for them would be a successful outcome. As expressed in the CMA's Defence, at para 225:

> "Continued litigation offered a real, concrete possibility of early independent generic entry, which (it is common ground) would have brought about a dramatic increase in competition and decrease in price. The continued litigation counterfactual was therefore appreciably more competitive than the Agreements."

333. We can readily accept that in the absence of the respective Agreements, it is likely that the GUK and Alpharma trials would have proceeded and resulted in a judgment. That was not disputed. However, the problem is that the result of each of those trials was uncertain, and in both the GUK and Alpharma cases it is impossible to say – nor does the CMA submit – that the generic company is likely to have won: see the Decision, paras 1.9 and D.28. For the purpose of the counter-factual, therefore, it is equally likely that GSK would have won, bringing none of the benefit on which the CMA relies.

334. As for the other counter-factual put forward in the Decision of an alternative, less restrictive settlement, in particular either a licence permitting entry with royalty payments or an early entry agreement, we have discussed those above: paras 257-262, 323-324 above. As already explained, we do not accept the Appellants' argument that they are to be excluded on the basis that Dr Reilly said they were unacceptable to GSK, since it is quite possible that GSK would have adopted a different approach if it was precluded from concluding agreements of the kind here at issue. But whether the parties would have reached such an alternative form of settlement is pure speculation. We consider that the CMA had no basis on the evidence to find that such an

alternative form of settlement would have been likely, nor does the Decision appear to reach such a conclusion.

335. However, Mr Turner argued that the fact that each of the two Agreements excluded the *potential* that the Anhydrate Patent would have been held to be invalid or not infringed at the patent trial means that the Agreements had the effect of restricting potential competition. As Mr Turner put it:

> "Our counterfactual is that the potential competition would have continued to exist."

And he proceeded to explain:

> "… the counterfactual is that a party that was preparing to enter [the market] by taking steps towards that aim would have continued to be able to take those steps with a real prospect, real concrete possibility of achieving the aim."

We think this neatly encapsulated the basis of the CMA's 'effects' case.

336. In support of that approach, Mr Turner relied on the *Visa Europe* case: see paras 92-93 above. It is correct that that was an effects case, and the appellants there argued that the Commission had erred in its approach to analysis of effects. However, the essence of the argument in that case was that Morgan Stanley could not be regarded as a potential competitor since it would not have taken the necessary steps to enter the market. Since it was accepted that Morgan Stanley had the ability to enter, the General Court found that this argument essentially amounted to the contention that Morgan Stanley lacked any intention to do so: paras 173-174 of the Judgment. That argument was rejected both on the facts and the law: paras 186-187. The factual basis of the infringement of Art 101 was a decision by Visa (as an association of undertakings, alternatively by agreement between its members) to refuse to accept Morgan Stanley as a member of the Visa network in Europe. Therefore, once it was determined that Morgan Stanley was a potential competitor, there was no question but that the condemned conduct had the effect of excluding it. In the counter-factual, the decision would have been the other way.

337. Mr Turner pointed out that there was no finding that Morgan Stanley was likely to have joined the Visa network. However, in the absence of the offending decision, it would have been free to do so. Therefore it was not merely probable but certain that the decision had the effect of excluding a potential competitor. Accordingly, we do not think that the *Visa Europe* case assists on this issue.

338. More pertinently, Mr Turner relied on Case AT.39612 – *Perindopril (Servier)*. This was a Commission decision of 9 July 2014. Perindopril was a blockbuster drug used in treatment of cardiovascular diseases and at the time was the most successful product of the Servier pharmaceutical group ("Servier"). The Commission held that Servier had infringed both Arts 101 and 102, in part on the basis of a series of patent settlements involving 'reverse payments' which it had concluded with generic challengers to its perindopril patents. The generic companies that concluded those agreements were also found to have infringed Art 101. *Servier* accordingly has obvious similarities to the present case.

339. The decision in *Servier* is exceptionally long and detailed, not least because of the number of parties and agreements involved. The Commission held that the various agreements between Servier and the generic companies gave rise to infringement of Art 101 'by object' but it proceeded to hold also that they were infringements 'by effect'. The Commission's approach to the counterfactual is set out at recital (1197):

> "If the patents had been enforced, … the courts may or may not have sided with Servier. The relevant counterfactual, to eliminating a potential competitor by a settlement akin to the investigated ones, is not that the patent would be invalidated, but that the competitive process consisting also in genuine patent challenges by potential competitors (as well as their legitimate interest in settling) would remain undistorted by inducements affecting the generic companies' incentives to compete. Paying potential competitors not to try to enter the market with their product is not based on any rights granted by patent law, nor on the strength of the patent, nor is it one of the legitimate means society has provided for the defence of patent rights."

340. Further, the Commission stated, at recital (1219):

> "According to the Guidelines on the application of Article 81(3), account must be taken of both actual and potential effects. In other words, the

> agreement must have likely anti-competitive effects (paragraph 24). In the *Visa* case, the General Court held that the Commission was correct in assessing the effects based on "*potential competition represented by Morgan Stanley [the excluded party] and on the structure of the market.*" The Commission will first establish the concrete effects of the settlement agreements on potential competition: the removal of the generic company as a potential competitor (which is also analysed under the rules for restrictions by object). In the second step, the Commission will then examine whether the elimination of a single potential competitor was likely to have effects on the competitive structure, and ultimately, for the consumers."

341. A detailed application of this approach can be seen in the context of some of the agreements being scrutinised. One concerned a settlement agreement between Servier and Niche/Unichem concluded on 8 February 2005. Niche Generics Ltd ("Niche"), a subsidiary of Unichem, was one of the most advanced generic challengers of Servier's perindopril at the time and expected to receive a UK MA in 2005. In June 2004, Servier started infringement proceedings against Niche on its process patents in the High Court. The court refused to countenance an interim injunction as Niche was not yet on the market but ordered a speedy trial, first scheduled for December 2004. It seems that the trial was concerned with infringement only, not validity, since Servier did not include a claim on its patent for the alpha crystalline form of perindopril ("the '947 patent") which Niche contended was invalid. Niche was indeed a party to an opposition procedure before the EPO on the '947 patent. The High Court hearing was subsequently postponed to February 2005 and in January 2005 negotiations on a settlement began. Agreement was reached on the day when the trial was due to start.[49] By the agreement Niche/Unichem agreed to restrict their ability to compete and not to challenge Servier's main perindopril patents, and Servier agreed to pay Niche £11.8 million, and further a subsidiary of Servier (Biogaran) agreed to pay Niche £2.5 million for the transfer to it of three product dossiers. It seems that the restrictions on Niche/Unichem lasted for the duration of the patents and accordingly they were more extensive than in the Agreements in the present case. See generally recitals (483)-(569), (1270)-(1279).

[49] Or possibly, just after it had started: recital (508).

342. The Commission's reasoning on restriction by effect of the agreement with Niche/Unichem is in section 5.2.2 of the decision. This includes the following passages:

> "(1390)…Absent the agreement, Niche/Unichem would have retained the competitive ability and incentives to pursue commercial strategies independently of Servier, taking into account the patent situation. The competitive threat from Niche/Unichem would have likely been maintained irrespective of whether the parties would settle on less restrictive terms, notably allowing earlier generic entry, or would not settle at all.
>
> (1391) Therefore, absent the agreement and its restrictive provisions, Niche/Unichem would have remained a prominent potential competitor to Servier through its opposition before the EPO, its challenge before the High court and its advance product development. In its reply to the Statement of Objections, Servier claims that the Commission refers to different actions that Niche could have undertaken but which would not have had the expected effects. In particular, Servier argues that (i) the outcome of the process patent litigation could not be anticipated, (ii) it was unlikely that Niche enters at risk, (iii) Niche would not launch a revocation action on the '947, (iv) withdrawal from the EPO opposition had no appreciable effect on competition, and (v) Niche had no interest or financial resources to oppose the beta patent). However, the counterfactual described by the Commission refers to a number of possibilities which were likely since Niche was well advanced in its development project with Matrix – had it not been for the settlement with Servier, Niche would have remained a competitive threat (through litigation and potential entry)."

343. The Commission applied analogous reasoning as regards the subsequent settlement agreement between Servier and Lupin Ltd ("Lupin") of January 2007. At that time, following a series of agreements entered into by Servier with different generic companies, there was still no generic perindopril on the market. Lupin was developing its own generic perindopril. It applied for a MA in January 2006 and was expecting to enter the market by April 2007. Lupin was one of the remaining opponents to the '947 patent before the EPO and in October 2006 it commenced invalidity proceedings challenging that patent before the High Court. Settlement negotiations with Servier started in December 2006. By the settlement reached in January 2007, Lupin agreed to discontinue its challenge to the '947 patent (both in the English proceedings and before the EPO) and to refrain from any further challenges of any of Servier's patents on perindopril, and not itself to enter the market with any perindopril (whether its own or sourced from third parties). Servier agreed to make payments to Lupin in the total amount of €40 million, ostensibly in consideration for the transfer of three process-patent applications, on which

Lupin however received a royalty-free back-licence. The Commission found that this sum was primarily an inducement to enter into the agreement since the commercial value of the patent applications for Servier was negligible. See generally recitals (974)-(1048), (1863)-(1978).

344. The Commission's reasoning on restriction 'by effect' of the agreement with Lupin is in section 5.6.2 of the decision. This includes the following:

> "(2032) In the reply to the Statement of Objections, Lupin tries to show that the Lupin Settlement Agreement had no actual effect on competition; however, the Commission does not make any inferences that Lupin would be an actual competitor absent the agreement. The counterfactual is that Lupin would remain a potential competitor to Servier.
>
> (2033) Therefore, in the absence of the restrictions in the agreement, Lupin would have remained a prominent potential competitor to Servier through its challenge to patent validity and/or its advanced product development, and its perindopril technology.
>
> ….
>
> (2052) …the Commission finds that the Lupin Agreement was such as appreciably to restrict potential competition among Servier and the generic companies and barred "*real concrete possibilities*" for Servier and Lupin to compete between each other or "*for a new competitor to penetrate the relevant market and compete with the undertakings already established*". By discontinuing Lupin's patent challenge, removing the possibility of launch at risk with Lupin's product or transfer of Lupin's technology to other generic companies, the Lupin Settlement Agreement appreciably increased the likelihood that Servier's significant market power would remain uncontested for a longer period of time and that consumers would forego a significant reduction of prices that would ensure from timely and effective generic entry."

345. Mr Turner submitted that the Decision here on effect is consistent with *Servier* and that the CMA's case is close to that case. We note that in *Servier* there was evidence that the '947 patent was considered by at least some of the parties to be weak, and that the restrictions in the settlement agreements there were very broad; but we accept that those features do not appear to be fundamental to the decision. Mr Flynn realistically and very properly accepted that *Servier* appears inconsistent with the Appellants' case on effect.

346. In practical terms, this line of reasoning suggests that even if we were able to find that GSK had a 70% chance of success in the patent proceedings, the settlements nonetheless had an anticompetitive effect since they precluded the

30% chance of GSK losing, or of concluding an alternative, less restrictive form of settlement. Indeed, in response to a question from Mr Malek as to whether there would still be a restriction by effect if three months later the Patents Court gave judgment for GSK in a related case against another generic company effectively upholding the patent, Mr Turner confirmed that this would not undermine the finding of restriction 'by effect' since that determination is made as of the time that the agreement is entered into.

347. This would also have the consequence that whereas in the infringement case there is a finding of restriction 'by effect', those who purchased the drug at the relevant time (e.g. the NHS) might not succeed in a subsequent claim for damages since they would have to prove that on the balance of probabilities they suffered loss, which would depend on what would have happened in the counterfactual, and thus the outcome of the hypothetical patent trial (unless such loss could be assessed as the loss of a chance, a possibility which was not explored before us). Mr Turner recognised this, and sought to justify it as follows:

> "…that comes back to the distinction one must be careful to draw analytically between restricting potential competition from moving forwards and the effects, as you have seen those are articulated by the Commission very clearly, recital (1219) and, on the other hand, a damages claim in court which by its nature is dealing with the question whether the claimant has suffered financial loss, which is a separate question and should not drive the analysis of the restriction in the first place in public law."

348. This approach seems to us to convert the test of a reasonable likelihood or probability of effects into a test of the probability of a possibility, and therefore to go beyond the established jurisprudence. We accept that in the absence of the Agreements there was a real *possibility* that the generic companies would have succeeded against GSK in the patent litigation. That was not really in dispute. Accordingly, if that were the correct test, we would uphold the Decision on effects. But if it is not, then we would find that the CMA's case on effects should fail.

349. Under sect 60 CA, the Tribunal is bound to take the Commission's decision in *Servier* into account but it is not binding. On that basis, Mr Flynn submitted that it is wrong and we should not follow it. However, it is under appeal to the

General Court, and judgment in those appeals is pending. There may well be further appeals to the CJEU. We recognise that the point is an important one. We think it is therefore appropriate to include in the reference a question whether the effects test under Art 101 is satisfied in such a situation.

(4) Are the GUK and Alpharma Agreements exempt under the Exclusion Order?

350. This question arises only if these two Agreements are otherwise caught by the Chapter I prohibition: i.e., on the assumption that GUK and Alpharma were potential competitors of GSK.

351. GUK, in particular, emphasised the importance of this contention, but it was raised by all the Appellants except Merck: ground 2 of GSK's Appeal; ground 4 of GUK's appeal; ground 3 of Actavis' appeal; and ground 3 of the Xellia/ALLC joint appeal.

352. As noted above, the Exclusion Order came into effect on 1 March 2000 (and was revoked with effect from 30 April 2005). Art 3 of the Order provides, succinctly:

> "The Chapter I prohibition shall not apply to an agreement to the extent that it is a vertical agreement."

353. A "vertical agreement" is defined in Art 2 of the Order as follows:

> ""*vertical agreement*" means an agreement between undertakings, each of which operates, for the purposes of the agreement, at a different level of the production or distribution chain, and relating to the conditions under which the parties may purchase, sell or resell certain goods or services…"

354. The CMA decided that the IVAX Agreement was exempt from the Chapter I prohibition as a vertical agreement under the Exclusion Order. The various Appellants submitted that the GUK and/or Alpharma Agreements were no different in that regard and so are similarly exempt.

355. The CMA held that the GUK and Alpharma Agreements did not satisfy the definition in Art 1 of "vertical agreements" since "GUK and Alpharma

respectively were not "*for the purposes of the agreement, at a different level of the production or distribution chain*" to GSK": Decision, para 10.40.

356. The various Appellants stressed the arrangements under the two Agreements for the supply by GSK (through IVAX) of generic paroxetine to, respectively, GUK and Alpharma for sale on the market. They sought to characterise the Agreements as distribution agreements, albeit entered into in settlement of litigation. However, Ms Demetriou QC, who argued this part of the case for the CMA, submitted that it was quite wrong to regard the GUK and Alpharma Agreements in this way. As she put it:

> "They are settlement agreements that settle patent litigation that was all about whether GUK and Alpharma could enter the market in competition with GSK. To that end, the agreements contain entry restrictions, restricting the freedom of GUK and Alpharma to sell paroxetine in competition with GSK."

357. In that regard, Ms Demetriou referred to the express restrictions on GUK and Alpharma selling paroxetine in the UK (save as manufactured by GSK) under, respectively, cl 8 of the GUK Agreement and cl 7 of the Alpharma Agreement: see para 188 above. Those were, she submitted, horizontal restrictions preventing the generic company from competing with GSK. The further elements of the two Agreements providing for supply of paroxetine were part of the total consideration for the entry restrictions and the settlement of the patent litigation.

358. We reject the Appellants' argument, essentially for the reasons expressed by Ms Demetriou. We have held above that the supply arrangements under the two Agreements were in substance and reality a form of non-cash value transfer to the respective generic companies; and that the value transfers were consideration for the respective generic company giving up its attempt to defeat GSK's patent actions and so enter the market independently. We also note that the OFT Guideline, *Vertical Agreements and Restraints* (OFT 419, 2000) on the application of the Exclusion Order states:

> "2.6 Undertakings often operate at more than one level of the production or distribution chain. An agreement between undertakings that operate at one or more of the same levels of the production or distribution chain may benefit from the exclusion for vertical agreements. *This will only be the case, however, where the agreement concerns only respective activities of those*

> *undertakings which are at different levels of the production or distribution chain.* The agreement can benefit from the exclusion because the undertakings involved each operate at different levels of the production or distribution chain 'for the purposes of the agreement.'
>
> 2.7 If, for example, a manufacturer which also distributes its product enters into a supply agreement with a distributor, that supply agreement may benefit from the exclusion even though the manufacturer also has sales activities which operate at the same level of the production or distribution chain as the distributor's activities. The two undertakings are operating at different levels of the production or distribution chain for the purposes of the agreement: the first is acting as a manufacturer and the second as a distributor. A supply agreement between them in these respective capacities (that is, as a manufacturer and as a distributor) may fall within the definition of a vertical agreement in the Exclusion Order and may therefore benefit from the exclusion." [Our emphasis]

359. Although not binding on us, those passages aptly describe a straightforward distribution agreement, containing no further restrictions, which would therefore be exempted under the Exclusion Order. The GUK and Alpharma Agreements were agreements of a wholly different kind.

360. Mr Kon argued that a non-compete restriction is not unusual in a distribution agreement, and pointed to the fact that under the then applicable EU Vertical Block Exemption Regulation ("VBER"), the inclusion of such a provision does not preclude an agreement from being a "vertical agreement". However, as we explain below, we do not consider that the GUK and Alpharma Agreements were 'vertical agreements' for the purpose of the VBER. But in any event, the VBER contained many further conditions limiting both the circumstances in which a vertical agreement may be exempt and the extent of the applicable exemption (severely limiting application of the exemption to an agreement between competing undertakings: Art 4; and as to the scope of a non-compete obligation that will qualify for exemption: Art 5(a)), and GUK notably did not seek to argue that the GUK Agreement fell within the scope of the VBER (which is applicable to the Chapter I prohibition as a parallel exemption: see para 80 above). We do not consider that the interpretation of the Exclusion Order is affected by the VBER.

361. That is sufficient to dispose of this ground of the appeals. But as strong reliance was placed on the CMA's treatment of the IVAX Agreement, it is

appropriate to consider that briefly. The IVAX Agreement is addressed in Annex B of the Decision. Mr Kon, in particular, drew attention to para B.111:

> "Although the IVAX-GSK Agreement did not contain any contractual commitment on IVAX's part not to launch an independent generic paroxetine, it is clear from the terms of the IVAX-GSK Agreement that the IVAX-GSK Agreement was not designed to co-exist with independent generic entry by IVAX (or any other party)…."

362. It is not in dispute, as there stated, that the IVAX Agreement does not contain any express restriction on independent entry by IVAX, let alone any provision resembling cl 8 of the GUK Agreement and cl 7 of the Alpharma Agreement. The reason why the IVAX Agreement was not considered to give rise to an infringement of the Chapter I prohibition is not set out in the Decision, but Ms Demetriou explained that the CMA took the view that the question of whether an agreement was a "vertical agreement" under the Exclusion Order is to be determined on the basis of its express terms. GUK submitted that this was not correct and that a purposive approach should be applied to the application of the Exclusion Order. However, as Ms Demetriou pointed out, that would not benefit GUK but would mean that the CMA was over cautious in its approach to the IVAX Agreement.

363. We do not need to decide whether the CMA was correct in its view that the IVAX Agreement fell within the Exclusion Order. For the reasons set out above, we have no doubt that neither the GUK Agreement nor the Alpharma Agreement was a "vertical agreement" for the purpose of the legislative definition, and accordingly they are not exempt under the Exclusion Order.

364. We should add, for completeness, that even if the GUK Agreement had fallen within the Exclusion Order, that would not have excluded it from infringement of Art 101 for the period 1 May – 1 July 2004, as found in the Decision.

(5) Are the GUK and Alpharma Agreements exempt under the VBER or by reason of individual exemption?

365. By ground 5 of its appeal, GSK contends that the GUK and Alpharma Agreements were in any event exempt from both the Chapter I prohibition and Art 101(1) in that:

(1) they fell within the terms of the then applicable VBER, which therefore exempted those agreements under Art 101(3) and also from the Chapter I prohibition by reason of the parallel exemption under sect 10 CA: para 80 above; and/or

(2) they satisfied the conditions for individual exemption in sect 9 CA, which mirror those of Art 101(3): para 79 above.

The other Appellants did not raise this ground in their appeals and it received relatively little attention during the hearing.

366. GSK accepts that it bears the burden of proof in establishing that its agreements fall within the block exemption or satisfy the conditions for individual exemption.

(a) *The VBER*

367. Art 2(1) of the VBER defined "vertical agreement" in terms mirrored by the UK Exclusion Order:

> "agreements … entered into between two or more undertakings, each of which operates, for the purposes of the agreement, at a different level of the production or distribution chain, and relating to the conditions under which the parties may purchase, sell or resell certain goods or services."

368. Rejecting this argument, the Decision states, at para 10.49:

> "The CMA has concluded that the GUK-GSK Agreement and the Alpharma-GSK Agreement were not '*vertical agreements*' within the scope of the 1999 VBER. In particular, and as set out at paragraph 10.40, those agreements specifically related to the 'settlement' (or deferral) of litigation that concerned a potential competitor's proposed market entry, and each of GUK and Alpharma (as potential competitors to GSK) expressly agreed to entry

> restrictions in return for the value transfers from GSK. Therefore GUK and Alpharma were not each '*for the purposes of the agreement, at a different level of the production or distribution chain*' to GSK."

369. For reasons set out above in our discussion of the Exclusion Order, we consider that this is correct. It is therefore unnecessary to consider the further ground on which the CMA relied, i.e. that the market share of GSK on the relevant market exceeded 30%, so that by reason of Art 3(1) the exemption under the VBER would not apply. That raises the question of market definition, which we consider below in addressing the Chapter II prohibition.

(b) *Individual exemption*

370. The criteria for individual exemption in effect require that four cumulative conditions are satisfied. The agreement must:

(i) contribute to improving production or distribution or to promoting technical or economic progress (commonly referred to as efficiencies);
(ii) allow consumers a fair share of the resulting benefits;
(iii) not impose on the undertakings concerned restrictions which are not indispensable to the attainment of those objectives; and
(iv) not afford such undertakings the possibility of eliminating competition in respect of a substantial part of the products in question.

371. Application of these criteria are discussed and explained in the Commission's Guidelines on the application of Art 81(3) [now Art 101(3)], to which the Tribunal must have regard, pursuant to sect 60(3) CA. These Guidelines state:

> "73. According to the third condition of Article [101(3)] the restrictive agreement must not impose restrictions, which are not indispensable to the attainment of the efficiencies created by the agreement in question. This condition implies a two-fold test. First, the restrictive agreement as such must be reasonably necessary in order to achieve the efficiencies. Secondly, the individual restrictions of competition that flow from the agreement must also be reasonably necessary for the attainment of the efficiencies.
>
> 74. In the context of the third condition of Article [101(3)] the decisive factor is whether or not the restrictive agreement and individual restrictions make it possible to perform the activity in question more efficiently than would likely have been the case in the absence of the agreement or the restriction concerned. The question is not whether in the absence of the restriction the agreement would not have been concluded, but whether more efficiencies are produced with the agreement or restriction than in the absence of the agreement or restriction."

372. By its Notice of Appeal, GSK alleges two particular efficiencies for the purpose of the first condition which are said to result from the GUK and Alpharma Agreements: (a) the substantial saving for the NHS: para 275 above; and (b) the reduction in the average price paid by pharmacies: para 293 above.

373. On that basis, it seems to us evident that the third and fourth conditions for exemption are clearly not satisfied. As regards the third condition, the argument of GSK appears, in effect, to be a contention that the GUK and Alpharma Agreements were distribution agreements which introduced authorised generic product onto the market. But on that basis, it is not indispensable for such an agreement that it should have included a requirement on the distributor to abandon its attempt to challenge GSK's patent.

374. As regards the fourth condition, the restrictions on GUK and Alpharma pursuing their challenges to GSK's patent and on entering the market with their own generic product while granting them only limited volumes of authorised generic supply, clearly gave rise to the possibility that GSK thereby precluded any competition from generic product for the balance of the market beyond the proportion accounted for by those volumes. And since we have found that GUK and Alpharma with their authorised generic supply were not in reality competing with GSK, we think that the two Agreements afforded GSK the possibility of controlling or eliminating competition over the market as a whole.

375. It is therefore unnecessary for us to consider the application of the first two conditions and we find that GSK failed to establish that the GUK and Alpharma Agreements benefit from individual exemption.

G. THE CHAPTER II PROHIBITION

376. A finding of infringement of the Chapter II prohibition comprises two elements: (1) a dominant position on a relevant market; and (2) conduct constituting an abuse of that position. However, the first element in turn involves two factors: (i) definition of the relevant market; and (ii) establishing a dominant position on that market.

377. The Decision held that the relevant market was the supply of paroxetine in the UK; that GSK held a dominant position in that market "at least" between January 1998 and November 2003; and that it abused that position from 3 October 2001 (the date of the IVAX Agreement) until 30 November 2003.

378. By ground 1 of its appeal, GSK challenged the finding of dominance, on the basis that the CMA erred as regards the relevant product market. By ground 6 of its appeal, GSK challenged the finding of abuse.

(1) Dominant position

379. The critical issue is the definition of the product market. As noted at para 9 above, Paroxetine belongs to the class of anti-depressants known as SSRIs. Under the Anatomical Therapeutical Chemical ("ATC") classification system, SSRIs comprise a fourth level class. GSK submitted that the relevant product market comprised all SSRIs and low dose venlafaxine. If that is the correct product market, then the CMA accepted that GSK was not dominant. Conversely, if the product market was paroxetine, as held by the Decision, then GSK accepted that it was dominant over the relevant period. Moreover, it is common ground that the question whether low-dose venlafaxine is included in the product market does not affect the determination of dominance.

380. There is no dispute that the geographic market was the UK, as held by the Decision.

381. The test for defining the product market was stated by the General Court in Case T-504/93 *Tiercé Ladbroke v Commission* EU:T:1997:84, para 81, in terms that have often been repeated:

> "the relevant product or service market includes products or services which are substitutable or sufficiently interchangeable with the product or service in question, not only in terms of their objective characteristics, by virtue of which they are particularly suitable for satisfying the constant needs of consumers, but also in terms of the conditions of competition and/or the structure of supply and demand on the market in question."

382. Further, after citing the relevant jurisprudence, the Tribunal in *Aberdeen Journals Ltd v DGFT* [2002] CAT 4, stated, at [96]-[97]:

> "96. The foregoing cases indicate that the relevant product market is to be defined by reference to the facts in any given case, taking into account the whole economic context, which may include notably (i) the objective characteristics of the products; (ii) the degree of substitutability or interchangeability between the products, having regard to their relative prices and intended use; (iii) the competitive conditions; (iv) the structure of the supply and demand; and (v) the attitudes of consumers and users.
>
> 97. However, this check list is neither fixed, nor exhaustive, nor is every element mentioned in the case law necessarily mandatory in every case. Each case will depend on its own facts, and it is necessary to examine the particular circumstances in order to answer what, at the end of the day, are relatively straightforward questions: do the products concerned sufficiently compete with each other to be sensibly regarded as being in the same market? Are there other products which should be regarded as competing in the same market? The key idea is that of a competitive constraint: do the other products alleged to form part of the same market act as a competitive constraint on the conduct of the allegedly dominant firm?"

383. Both the Commission's Notice on the definition of relevant market, OJ 1997 C372/05, and the OFT's Guideline on Market Definition (OFT 403, 2004; adopted by the CMA, 2012) make clear that the primary focus for consideration is demand-side substitutability. In the present case, it is not suggested that supply-side substitutability is relevant.

384. A frequent framework for defining the market is to apply the 'SSNIP' test: i.e., on the assumption that there was a monopoly in the supply of the focal product, would a small but significant (e.g. 5-10%) non-transitory increase in price lead sufficient purchasers to switch to another product such that the increase was not profitable because of the loss in sales?[50] That was the framework which the CMA purported to adopt in the present case: see Decision, para 4.21. However, aside from the question whether adequate and sufficiently robust data are available, there are two practical difficulties with applying a SSNIP test, even conceptually, in the present case. First, there is the so-called 'cellophane fallacy':[51] where the supplier has already been able to price the focal product at substantially above competitive levels, a further increase in price may induce customers to switch to other products but it would be wrong to conclude from this that those other products are in the

[50] If it would, then that other product is to be included in the product market, and the exercise is repeated, incrementally. See the OFT Guideline, paras 2.5-2.11.
[51] So called after a celebrated US case involving cellophane products: *US v E.I. Pont de Nemours & Co* 351 US 377 (1956).

same market (such that the supplier therefore lacked market power). Secondly, with a prescription medicine, the choice of product is not made by the person who pays for it: the prescribing doctor chooses the drug, whereas it is the NHS, by reimbursing the pharmacy, which pays the price. Hence, at least at the relevant time, GPs were relatively insensitive to price: Decision, para 3.95; and they are therefore unlikely to be affected in their prescribing decision by a 5-10% price increase.

385. In Case C-457/10P *AstraZeneca v Commission* EU:C:2012:770, the CJEU considered the approach to market definition concerning a pharmaceutical drug, in a case where the Commission had found an abuse of dominance under Art 102. The case concerned a pioneering, omeprazole-based medicinal product used in the treatment of certain gastrointestinal conditions, marketed by AstraZeneca ("AZ") under the brand "Losec", for which the primary patent protection expired in 1993. Losec was the pre-eminent drug of the type described as 'proton pump inhibitors' ("PPIs"). GUK and another subsidiary of Merck complained about certain practices of AZ which they contended prevented them from bringing generic versions of omeprazole to the market thereafter. The critical question was whether PPIs were in the same product market as other products used for treatment of some of the same gastrointestinal conditions, in particular histamine receptor antagonists ("H2 blockers"), in which case AZ was not dominant. The Commission held that the product market comprised only PPIs.[52] This conclusion was upheld by the General Court and then, on further appeal, by the CJEU, which stated at para 59 of the judgment:

> "…the market definition upheld by the Commission was reached after an overall appraisal of all the evidence on which the Commission based its assessment, which includes other price indicators, such as the fact that the strongest impact on the demand for omeprazole produced by AZ was caused by the price of the generic versions of omeprazole and, to a lesser extent, that of the other PPIs, and factors not relating to price, such as the greater efficacy of PPIs, the differentiated therapeutic use of PPIs and H2 blockers, the asymmetrical substitution trend that characterised the growth in sales of PPIs and the corresponding decrease or the stagnation in sales of H2 blockers and the particular circumstances observed in Germany and the United Kingdom."

[52] COMP A.37.507 *AstraZeneca* (2003) decision of 15 June 2005.

386. The reference to greater efficacy and differentiated therapeutic use relates to the finding that "PPIs were generally prescribed to treat severe forms of gastrointestinal conditions linked to hyperacidity while H2 blockers were generally prescribed to treat their mild or less serious forms": para 41 of the judgment, and see recitals (382)-(386) of the decision. The reference to the impact on demand and the circumstances in Germany and the UK relates in particular to the Commission's 'natural events' analyses. The Commission found that in Germany, the launch of a rival PPI was followed by a 16% decline in the price of Losec but had no effect on the falling trend in the price of H2 blockers: recital (422); that in both Germany and the UK, entry of a generic H2 blocker (ranitidine) was followed by a decline in H2 blocker prices but had no effect on the price or sales of Losec: recitals (423) and (452)-(456); and that in Germany, the launch of generic omeprazole led to a sharp decline in Losec's sales volume and market share in about five months, and on the share of all PPI firms: recital (425).

387. Here, the Decision applied both (a) a qualitative analysis and (b) a quantitative analysis.

(a) Qualitative analysis

388. The Decision found that there were no real distinctions based on the patient's condition as to which specific anti-depressant medicine would be preferred by prescribing doctors and that GPs took a wide range of individual factors into account: para 4.48. The Decision also cited the views of GSK marketing personnel that at the time they viewed Lundbeck's Cipramil and Cipralex (both SSRIs) as the closest competitors to Seroxat: para 4.50. As regards internal documents, the Decision stated, at para 4.61:

> "Overall, the CMA considers that GSK's documents demonstrate that GSK perceived there to be a number of competing products in the relevant treatment area, with citalopram, fluoxetine and escitalopram [all SSRIs] being most frequently cited."

389. The Decision concluded the "qualitative" analysis as follows:

> "4.63 The CMA considers that because GPs may value different characteristics differently and may therefore differentiate between products that appear to have similar characteristics, considering functional substitutability is insufficient to determine which products are capable of exerting a significant competitive constraint on paroxetine as this only provides information on how medicines may interact *in theory*, and is by itself inconclusive. Given this, and GPs' apparent lack of price awareness, it is necessary to consider actual consumption patterns as a means of determining whether, in practice, the degree of product differentiation was such that GPs would substitute between products to an extent that would prevent a monopolist supplier of paroxetine from sustaining a SSNIP." [Emphasis in original]

(b) Quantitative analysis

390. The CMA relied in the Decision in particular on a series of 'natural events' analyses. In particular:

(1) the entry of generic fluoxetine in Q4 1999: this resulted in a sharp fall in fluoxetine prices in the following nine months and a significant increase in the price differential between fluoxetine and paroxetine, but that had a very limited impact on paroxetine sales: Decision, para 4.86;

(2) the launch of Cipralex (escitalopram) in May 2002: there was a downward trend in sales of paroxetine between June 2002 and March 2005 but the CMA considered that no conclusion could be drawn from that since this coincided with negative reports about withdrawal symptoms from paroxetine. Further, GSK did not respond by reducing the price of Seroxat but only decreased its marketing investment: Decision, paras 4.87-4.89;

(3) the entry of generic citalopram in September 2003: this was just three months prior to the entry of generic paroxetine, and the CMA simply stated (Decision, paras 4.91-4.92):

> "The CMA considers that the resulting falls in paroxetine and citalopram prices are each the consequence of generic competition for each medicine respectively, and do not indicate that the generic price fall relevant to citalopram acted to constrain the prices of paroxetine.
>
> … There is no evidence in the evolution of prices during the period between 2000 and 2003 that paroxetine and citalopram were competing closely."

(4) the entry of independent generic paroxetine in November 2003: this led to a marked decrease in average paroxetine prices and GSK's sales volumes of both 20mg and 30mg Seroxat.

391. The CMA's conclusion of its quantitative analysis is expressed as follows, at para 4.94:

> "The impact of independent generic paroxetine entry demonstrates that, prior that event, competition from all other medicines in the treatment area had been insufficient to prevent GSK, as the only supplier of paroxetine, from sustaining prices and profits that were significantly higher than it could sustain following independent generic entry. An analysis of prior events (that of generic entry relevant to citalopram and fluoxetine, and the launch of escitalopram) suggests that other medicines constrained paroxetine prices and profits to a much lesser degree. Any constraint that other medicines did impose should therefore be considered in the context of paroxetine profits having at that time been at supra-competitive levels, and of other medicines becoming substitutes to a greater degree than they would have had prices and/or marketing of paroxetine been closer to competitive levels."

392. In its appeal, GSK relied as regards the qualitative position on the evidence of Prof Young, which was not challenged. This showed conclusively that there were no significant therapeutic differences between paroxetine and other SSRIs, and that although there were some conditions for which paroxetine was uniquely more suitable those were very rarely diagnosed by GPs separately from depression. GSK also emphasised the witness evidence from Ms Nicholson, who was its Seroxat Marketing Manager from December 2002. She testified to the promotional and marketing efforts in which GSK engaged to meet the challenge it felt from, in particular, Cipramil and Cipralex.

393. Altogether, GSK strongly criticised the Decision as relying on quantitative evidence based on the situation after generic entry, and in effect excluding qualitative evidence.

394. The question of market definition was addressed by the two expert economists called by GSK and CMA, Dr Stillman and Prof Shapiro, who gave their oral evidence on this issue concurrently in a 'hot tub'. We found the discussion between them and their response to the Tribunal's questions very helpful, and neither side's Counsel sought to conduct further cross-examination.

395. The approach articulated by Prof Shapiro was rather more sophisticated than that set out in the Decision. In his opinion, once paroxetine became 'genericised', then the relevant market was constituted by paroxetine itself, since generic paroxetine was then the prime constraint on the pricing of Seroxat. The generic product manifestly had an effect very significantly greater than any other SSRI. Before genericisation, in Prof Shapiro's view the question of what constitutes the relevant market cannot be answered without considering what is the conduct under scrutiny, and the answer therefore may not be the same in all cases. Thus, if the impugned conduct was a product tie (e.g., cp. *Genzyme Ltd v OFT* [2004] CAT 4: supply of a drug only bundled together with the provision of homecare services), Prof Shapiro accepted that the approach of GSK may be correct and the relevant product market would comprise all SSRIs. But if, as here, the issue concerns conduct directed specifically at excluding independent generic paroxetine from the market, then it would be inappropriate and misleading to leave generic companies out of consideration when seeking to define the market just because they were not on the market.

396. Dr Stillman agreed that after generic entry, the product market would be paroxetine (although Mr Flynn in his closing submissions did not accept that view). He also agreed that the product market may receive a different definition in the case of a merger, since then it is forward-looking and takes account of future market development, as compared to an abuse of dominance case, which is backward-looking. But he considered that one cannot have the market defined differently in an abuse case according to what conduct was under scrutiny, such that a company could be dominant for some purposes but not for others. Dr Stillman said that was an unorthodox view and would lead to considerable business uncertainty. He also pointed out that if the CMA's approach were followed, and the "competitive price" yardstick were taken to be the generics price, this would ignore the reality that for patented pharmaceuticals the competitive price has to be considered over the whole product life cycle. Professor Shapiro agreed, in response to questions from Mr Glynn, that this was the correct way to conceptualise the competitive price for such patented products.

Discussion

397. In deciding this issue, we think it is important to bear in mind that market definition is not an end in itself: it is a tool for determining the question of dominance: see e.g. the OFT Guideline on Market Definition, para 2.1.

398. In the present case, the facts underlying the question of market definition are not in dispute. The real issue is as to the appropriate conceptual approach.

399. We see considerable force in GSK's criticism of the Decision. Even on its own terms, the qualitative analysis in the Decision does not establish real therapeutic distinction between paroxetine and the other SSRIs. That is not to be dismissed as somehow "theoretical". This is the position as a matter of fact, now conclusively demonstrated by the evidence of Prof Young. As regards the quantitative analysis, much effort seems to be devoted in the Decision to showing the obvious: that there was little effective price constraint from other SSRIs compared to the effect once independent generic paroxetine entered the market. But that is the inevitable consequence of the lack of price sensitivity of prescription only medicines on the UK market: see para 384 above. The Decision takes the view that this shows that paroxetine faced little competitive constraint from other drugs. If that simple approach in itself was sufficient to define the product market, then almost every valuable medicine which was subject to patent protection but which eventually attracted generic entry once the patent expired would constitute a distinct market, with the consequence that the patent-holder was therefore dominant in that market. We agree with Dr Stillman that this would be a material change to the "IP bargain" and one that might adversely affect the economic purpose of patent legislation.

400. It is true that in *AstraZeneca* the Commission also relied on natural events concerning price impacts. However, in the first place, the analysis there was carried out in the context where the Commission found that there was some price sensitivity. The Commission stated, at recital (406):

> "…while the effect of relative price differences (especially between different categories of molecules such as PPIs versus H2 blockers) matters relatively speaking less as a competitive parameter in pharmaceutical prescription

> markets, price competition has become increasingly important during the 1990s in the EEA, chiefly as a result of cost-containment measures imposed by the public authorities (recital (368)). Therefore, despite the relatively low cross price elasticity of demand between different product categories in pharmaceutical prescription markets, the effect on demand substitution of changes in relative price differences between PPIs and H2 blockers examined by the Correlation study submitted by the complainant is not irrelevant for determining whether PPIs or H2 blockers form part of the same or distinct markets."

There is no equivalent finding in the present case. Secondly, the decision on market definition in *AstraZeneca* was not based on quantitative analysis alone but, as Mr Flynn emphasised, also rested on strong qualitative evidence that there was a clear therapeutic differentiation between PPIs and H2 blockers and that PPIs were considered therapeutically superior.

401. In our view, it is artificial to rely on the SSNIP test, even as a framework, when a particular feature of this market is that demand for the product is not price-sensitive. Although frequently useful, either conceptually or in actual application, it is not a necessary approach to market definition. As the General Court stated in Case T-699/14 *Topps Europe Ltd v Commission* EU:T:2017:2, when rejecting criticism of a Commission decision for having failed to use the SSNIP test (at para 82):

> "The SSNIP test may also prove unsuitable in certain cases, for example in the presence of the 'cellophane fallacy', that is, the situation where the undertaking concerned already holds a virtual monopoly and the market prices are already at a supra-competitive level, or where there are free goods or goods the costs of which is not borne by those determining the demand."

Accordingly, we do not accept the CMA's approach of using the price levels of generic versions of other SSRIs or of paroxetine after generic entry as the basis for the application of a SSNIP test. The critical question, as stated in *Aberdeen Journals*, is to identify what other products provided a competitive constraint to the conduct of the potentially dominant firm.

402. In our judgment, Prof Shapiro's approach is to be preferred, largely for the reasons that he gave: see para 395 above. 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 (see para 18 above) 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.

403. We recognise that this approach is novel. However, it is well recognised that market definition is contextual: see e.g. Rose and Bailey (eds) *Bellamy & Child*: *European Union Law of Competition* (7th edn, 2013), para 4.014. The definition sought is of the *relevant* market: this is not an absolute but should reflect relevance to the issue under consideration, and can vary accordingly.

404. Therefore, since here the conduct of GSK that is under scrutiny concerns its agreements with a succession of generic companies whereby they would not introduce their independent generic product onto the market, in our judgment the relevant market for the purpose of the competitive assessment should encompass that generic product. Given the dramatic price and volume effect on GSK's Seroxat of such generic entry, the competitive constraint from the generic product far outweighs any pressure on GSK from other SSRIs, notwithstanding their therapeutic equivalence.

405. The *AstraZeneca* case provides some support for taking the generic companies that have not entered the market into account in such a scenario. That too was

a case of alleged exclusionary conduct towards generic companies. One of the 'natural events' relied on by the Commission, and not criticised in the judgments on appeal, was the effect of the launch of generic omeprazole in Germany on the volume and market share held by Losec: see para 386 above. The Commission states, at recital (425):

> "This 'natural event' clearly demonstrates that Losec was not constrained by H2 blockers nearly as much as by the closest substitute, i.e. generic omeprazole – at least at this point in time."

However, that generic omeprazole entered the German market only in April 1999, whereas the alleged abusive conduct under scrutiny had ceased at the end of 1997: recital (916).

406. Moreover, the issue of market definition arose also in *Servier*, where it will be recalled the abuse similarly concerned 'reverse payment' patent settlements and the Commission held that Servier had thereby abused a dominant position contrary to Art 102 as well as being in violation of Art 101. Rejecting Servier's argument that the relevant product market comprised all angiotensin converting enzyme (ACE) inhibitors used for the treatment of cardiovascular disease, the Commission held that the relevant market there comprised only original and generic perindopril. While a range of matters were considered, given the nature of the alleged abuse the Commission relied in particular on the extent of the competitive constraint from the generic product, although generic companies were not yet on the market. The decision states:

> "(2545) The limited effectiveness of constraints imposed by other medicines stands in stark contrast to the strength of the constraint expected from (and eventually introduced by) perindopril's own generics. In principle, generic perindopril could challenge all the existing sales of original perindopril. The exposure of Servier's perindopril to the generic threat was neither limited by the existence of the continued-use patient base nor by the doctor's inertia (even if some doctors may prescribe the originator's brand only). Moreover, the regulatory frameworks promoted price competition between original and generic perindopril.
>
> (2546) The generic constraint must be regarded as critical for the assessment of the relevant product market in the case in which the objected practices were aimed at neutralizing the very same constraint. The fact that the generic constraint outweighs by an order of magnitude all other potential constraints facing original perindopril naturally leads to the finding of a narrow market comprising only the medicine in question. If compared to the generic constraint, other sources of constraints for perindopril were insufficient to

> exercise the effective competitive pressure [*sic*]. Elimination of the generic constraint can be shown to have significant effects in terms of the overall customer spending on perindopril. This being said, the relative strength of various constraints is an empirical question and may not necessarily be similar in other cases, in particular those in which a generic constraint is less eminent."

Although not binding on us, we take that into account and it supports the view we have reached.

407. We consider that there is a further reason for finding that paroxetine constituted the relevant product market at the relevant time, although not one set out in the Decision. There were independent suppliers of paroxetine in the UK over the relevant period in the form of PIs. Prior to the Agreements, PIs accounted for about 40% of sales of 20mg paroxetine in the UK: see the graph at para 272 above. It is clear from Mr Sellick's evidence that GSK responded to the competitive pressure from PIs by offering significant price discounts or rebates on 20mg Seroxat, through the 'brand equalisation' deals it concluded through its sales representatives with pharmacies around the country. Mr Sellick explained how the extent of the rebate an individual pharmacy received reflected an assessment of the degree to which it would otherwise purchase PI product. Moreover, although 30mg paroxetine accounted for some 27% of NHS expenditure on paroxetine in 2001-02,[53] GSK offered no such deals on the 30mg product. Mr Sellick was not aware of the reason, but since the rationale for these deals was the threat from PIs, the likely explanation is that there were no PIs of the 30mg dosage. This supports our conclusion that the significant competitive constraint on GSK's Seroxat in economic terms came from paroxetine and not other SSRIs.

408. We should add that GSK sought to rely on the Court of Appeal decision in *Chemistree Ltd v Abbvie Ltd* [2013] EWCA Civ 1338, concerning a refusal to supply a pharmacy business with a particular drug used as one of the elements in antiretroviral combination therapy for the treatment of HIV patients. However, in that case there was evidence of the significant effort made to

[53] The proportion of GSK's sales by value of Seroxat (net of discounts) in 2001-02 accounted for by the 30 mg dosage was difficult to calculate with precision because of difficulties over the data, but on the basis of figures put forward by GSK during the hearing it appears to have been at least 30%.

encourage doctors to have regard to the price of antiretroviral drugs when deciding what to prescribe, so price was a genuine factor which made a SSNIP test analysis appropriate. That is a very different situation from the present and we therefore do not derive assistance from that judgment.

409. Accordingly, we would uphold the Decision on market definition, albeit on a rather different basis from the CMA's reasoning. However, *Servier* is currently under appeal and Mr Flynn submitted that on this issue also it is wrong. As we have observed above, any judgment of the General Court will be binding on the UK courts but there may be a further appeal in *Servier* to the CJEU. Since we have decided to make a reference to the CJEU, we think it is therefore appropriate to include in the reference this question of market definition.

(2) Abuse

410. Insofar as the finding of abuse concerns GSK's entry into the GUK and Alpharma Agreements, it effectively depends on the same grounds as those relied on to establish a breach of the Chapter I prohibition. The CMA accordingly accepted that if its finding of a violation of the Chapter I prohibition is annulled, unless that should be on the narrow basis of the applicability of the Exclusion Order (an argument we have dismissed), then its decision under the Chapter II prohibition falls with it. Therefore, to that extent the resolution of the Chapter II case depends on the answers to the questions being referred to the CJEU.

411. However, as stated above, the CMA held that the abuse committed by GSK started on 3 October 2001 with the entry into the IVAX Agreement. Therefore, even if the decision under the Chapter I prohibition were to be upheld, it is necessary to address specifically the circumstances of the IVAX Agreement. The CMA's analysis of the position of IVAX and the IVAX Agreement is in Annex B to the Decision.

412. There are three questions to be considered:

(a) Was IVAX a potential competitor of GSK?

(b) Since it was the introduction of authorised generic supply pursuant to the IVAX Agreement which led to the reclassification of paroxetine under the Drug Tariff, does the resulting benefit to the NHS mean that entry into the IVAX Agreement was not an abuse?

(c) Since the CMA considered that the IVAX Agreement came within the Exclusion Order and thus was exempt from the Chapter I prohibition, can the conduct of GSK in entering into that agreement nonetheless constitute an abuse?

(a) ***Was IVAX a potential competitor?***

413. GSK never obtained an interim injunction against IVAX, so the arguments particularly relied on by GUK and Alpharma in that regard obviously have no application. The submissions of GSK that IVAX was not a potential competitor concerned the source of supply of paroxetine. GSK in particular contended that IVAX would not in fact have been able to obtain paroxetine and therefore lacked any realistic ability to enter the market at the time of the IVAX Agreement.

414. We have already quoted Dr Reilly's account of his meetings in 2000-01 with Mr Blanksby and Mr Clark of IVAX, explaining why GSK regarded IVAX as a serious threat at the time: para 21 above. However, GSK's position in these proceedings is that IVAX was bluffing and that it did not have a non-infringing product.

415. It appears from the statement made by Mr Blanksby to the CMA in the course of its investigation that, whatever may have been said to Dr Reilly, the source actually being relied on by IVAX was not an in-house product but supplies from Tillomed Laboratories Ltd ("Tillomed"). It is clear that as well as negotiating with GSK, IVAX engaged in negotiations with Tillomed, which had a MA for paroxetine in the UK. At the beginning of October 2001, IVAX concluded Heads of Agreement with Tillomed, whereby Tillomed was to grant

IVAX an exclusive right to its MA in return for royalty payments and Tillomed would supply 20 mg paroxetine to IVAX at the price of £8.45 per pack, with all other terms of supply to be agreed.[54] The Heads of Agreement were expressed (by cl 5) to be legally binding and committed the parties to enter into a full agreement by 31 October 2001.

416. As matters transpired, IVAX did not proceed to take supplies from Tillomed since at the same time it was negotiating with GSK. But we think it is almost inconceivable that IVAX and Tillomed would have got as far as concluding formal Heads of Agreement in those terms if Tillomed did not have supplies to offer to IVAX and if IVAX had not intended to take them in the event that its discussions with GSK proved unsuccessful. Tillomed stated to the OFT in the course of the investigation that it had planned to source the paroxetine from A/S Gea ("Gea"), a Danish subsidiary of the Hexal group (Tillomed was 50% owned by that group at the time). Although in argument GSK sought to make much of production problems which Gea had experienced in Denmark, leading to a product recall in June 2001, we consider that Tillomed would not have signed the binding Heads of Agreement over three months later if it was not confident of its ability to supply the product.

417. Mr Blanksby explained, when interviewed by the CMA, that IVAX's preferred option was to reach a deal with GSK, as then it was sure it would have no patent problems; but that if it was unsuccessful with GSK, it was looking to get supplies from Tillomed. That is borne out by the contemporary documents. Mr Blanksby also said that as the original IVAX Agreement was for only 12 months, IVAX felt it was important to maintain good relations with Tillomed in case it needed to turn to Tillomed for supplies thereafter. We also note that in his evidence in the Alpharma litigation, on 30 July 2002, Dr Reilly said that if not prevented by GSK's patents, Tillomed was one of a number of companies that could enter the UK market with generic paroxetine "almost immediately."

[54] The document is dated 4 October 2001, but Mr Blanksby said he would not have signed it after he signed the IVAX Agreement, which was dated 3 October 2001. It may therefore be misdated.

418. Accordingly, we think that IVAX would in all probability have been able to source independent paroxetine. It is clear from Dr Reilly's evidence that GSK regarded IVAX as a potential competitor at the time and, in all the circumstances, we consider that it was right to do so.

419. We consider that if IVAX had not concluded the IVAX Agreement with GSK, it would have sought to enter the market independently and GSK would have commenced patent infringement proceedings against IVAX. It is uncertain which side would have succeeded in those (hypothetical) proceedings.

(b) ***The Drug Tariff***

420. The effect of the IVAX Agreement was to introduce 770,000 packs of 20 mg generic paroxetine onto the UK market over the 12 months from 1 December 2001, which led to the reclassification of paroxetine under the Drug Tariff from June 2002: see para 275 above. As we have explained, that led in turn to a significant saving for the NHS by reason of the significantly lower reimbursement price.

421. This self-evidently was a benefit for the NHS, although it did not produce the same savings that would result from unrestricted and independent generic entry, which would cause (and of course eventually did cause) a dramatic fall in the price.

422. Although under the IVAX Agreement there was no contractual restriction on IVAX entering the UK market independently (by contrast with the position under the GUK and Alpharma Agreements), we have no doubt that this was the intention and understanding of the parties. Dr Reilly was clear that GSK entered into the IVAX Agreement because it wished to avoid IVAX launching an independent product and the need to embark on litigation in an attempt to enforce its patent rights. GSK did not seek to suggest otherwise in its appeal.

423. The IVAX Agreement was for an initial term of 12 months but the parties clearly envisaged that it might be extended. Cl 3.1 provided that:

> "[GSK] agrees that any extensions shall be offered on a sole basis on similar terms to those included herein and that IVAX shall be offered a right of first refusal on the supply of the PRODUCT for an extended period."

The IVAX Agreement was indeed twice extended: by the 1st Addendum on 15 February 2002 by two years, so as to expire on 30 November 2004; and by the 2nd Addendum on 12 September 2002 so as to expire on 13 March 2005.

424. The CMA calculated that the total amount of the value transfer made by GSK to IVAX was at least £17.9 million, comprising the total of £10.15 million in "promotional allowances" paid over the full duration of the Agreement and the profit margin sacrificed by GSK in respect of sales of the volume of paroxetine which it supplied to IVAX:[55] Decision, para B.63. For IVAX, in addition to the substantial cash payments, IVAX received virtually assured profits on that volume of paroxetine, so long as GSK succeeded in preventing any other independent entry, without the risk of having to overcome a patent challenge from GSK.

425. In *Streetmap.Eu Ltd v Google Inc* [2016] EWHC 253 (Ch), the test to be applied when considering the question of effect, for the purpose of abuse of dominance, was formulated as follows, at [88]: "The impugned conduct must be reasonably likely to harm the competitive structure of the market." Neither side in the present appeal dissented from that approach. Here, in the absence of the IVAX Agreement, we think it is at least reasonably likely that IVAX would have launched an independent product, and that GSK would then have commenced patent proceedings against IVAX. But whereas the benefit to the NHS of the authorised generic supply under the IVAX Agreement was certain, the significantly greater benefit of successful independent generic entry was uncertain since it was dependent on what would have happened in those putative proceedings.

[55] Estimated at between £7.7 million and £12.1 million, depending on the proportion of sales that were at the expense of PIs or of Seroxat sold by GSK in the UK: Decision, para B.70.

426. Accordingly, this aspect of the case under the Chapter II prohibition is subject to a similar issue of principle as the case under the Chapter I prohibition. There is a possible distinction, however, in that 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. However, if that is wrong and abuse were to be considered separately as regards each Agreement, the effect of the IVAX Agreement on the NHS Drug Tariff could be material to assessment of that Agreement. Since we are referring the questions of object and effect as they arise in the context of the Chapter I prohibition for a preliminary ruling, we consider that it is appropriate to refer the analogous question arising under the Chapter II prohibition, with this potential qualification.

(c) ***The Exclusion Order***

427. In considering the Exclusion Order for the purpose of the Chapter I prohibition, we did not find it necessary to determine whether or not the IVAX Agreement fell within its terms. GSK contended that the IVAX Agreement was so excluded, and that this showed that a vertical agreement such as this raised no competition concerns. GSK submitted that it is important to interpret Arts 101 and 102 (and thus the Chapter I and Chapter II prohibitions) consistently, because they serve the same ends. To characterise a vertical agreement covered by the Exclusion Order as an abuse would, Mr Flynn submitted, "effectively over-ride[…]" the legislative provision, which is impermissible.

428. For the purpose of this submission, GSK relied on the judgment of the Court of First Instance in Case T-51/89 *Tetra Pak v Commission* EU:T:1990:41. There, the Commission found that the appellant ("Tetra Pak") was in breach of Art 86 (now Art 102), through the acquisition of an exclusive patent licence

covering a sterilisation technique for the special machines used in UHT milk packaging. The licence fell within the then Commission block exemption for patent licensing agreements (Regulation 2349/84) and was therefore exempt from Art 85 (now Art 101). Tetra Pak argued that it could not therefore violate Art 86. That argument was rejected by the Court, and Mr Flynn pointed to para 24 of the judgment, where the Court referred to an additional element, extraneous to the patent licence itself, which had originally been granted to a third party. That additional element was the acquisition of an assignee of the licence by Tetra Pak, which thereby strengthened the dominant position which Tetra Pak held in the market. By contrast, argued Mr Flynn, the finding of abuse in the present case is directed at the IVAX Agreement itself, and such an "additional element" is lacking.

429. We reject this submission as fundamentally misconceived. It is axiomatic that the Exclusion Order does not provide exemption from the Chapter II prohibition. If it was intended to do so, the Order would have said so. As the OFT Guideline (para 383 above) succinctly states, at para 1.9:

> "There is no exclusion from the Chapter II prohibition for vertical agreements and restraints."

430. Far from the *Tetra Pak* case supporting GSK's contention, we consider that it established the opposite. The Court made clear that, as a matter or principle, Arts 85 and 86 operate independently, stating at para 25:

> "…in the scheme for the protection of competition established by the Treaty the grant of exemption, whether individual or block exemption, under Article 85(3) cannot be such as to render inapplicable the prohibition set out in Article 86. This principle follows both from the wording of Article 85(3) which permits derogation, through a declaration of inapplicability, only from the prohibition of agreements, decisions and concerted practices set out in Article 85(1), and also from the general scheme of Articles 85 and 86 which, as noted above, are independent and complementary provisions designed, in general, to regulate distinct situations by different rules. Application of Article 85 involves two stages: a finding that Article 85(1) has been infringed followed, where appropriate, by exemption from that prohibition if the agreement, decision or concerted practice in question satisfies the conditions laid down in Article 85(3). Article 86, on the other hand, by reason of its very subject-matter (abuse), precludes any possible exception to the prohibition it lays down.…"

431. The Court proceeded to consider whether a finding of exemption under Art 85(3) – corresponding to sect 9 CA – was nonetheless relevant in practice to determination of the application of Art 86. The judgment notes that where it was found that an agreement was entitled to individual exemption that would be material because it meant that a determination had been made by assessment of the particular agreement that it satisfied the cumulative conditions of Art 85(3). By contrast, where an agreement was exempt because it fell within the terms of a block exemption, that was irrelevant to the application of Art 86:

> "29. …unlike individual exemptions, block exemptions are, by definition, not dependent on a case-by-case examination to establish that the conditions for exemption laid down in the Treaty are in fact satisfied. In order to qualify for a block exemption, an agreement has only to satisfy the criteria laid down in the relevant block-exemption regulation. The agreement itself is not subject to any positive assessment with regard to the conditions set out in Article 85(3). So a block exemption cannot, generally speaking, be construed as having effects similar to negative clearance in relation to Article 86. The result is that, where agreements to which undertakings in a dominant position are parties fall within the scope of a block-exemption regulation (that is, where the regulation is unlimited in scope), the effects of block exemption on the applicability of Article 86 must be assessed solely in the context of the scheme of Article 86."

432. Even if the IVAX Agreement came with the Exclusion Order (as to which we express no view), that would be akin to its benefitting from a block exemption and would not result from an individual assessment of its effect. Accordingly, that would have no bearing on determination of whether GSK abused its dominant position by entering into the IVAX Agreement.

H. RIGHTS OF DEFENCE

433. GUK, Merck and Actavis argued that the passage of time between the conclusion of the relevant Agreements and the opening of the investigation compromised their rights of defence, such that the Decision should be set aside. GUK also argued the Decision differed in material respects from the Statement of Objections ("SO"), such that the CMA should have issued a further supplementary SO. This challenge formed ground 5 of GUK's notice of appeal, ground 3 of Merck's notice of appeal and ground 4 of Actavis' notice of appeal. Separately, GSK and Xellia/ALLC argued that the passage

of time should constitute a mitigating factor resulting in the total or partial reduction of the penalty. If the Decision on infringement stands, the significance of any delay in the proceedings to the imposition or level of penalty is a distinct issue, which we therefore will consider separately.

434. The GUK and Alpharma Agreements were made in 2002 and terminated in 2004. The OFT commenced its investigation in August 2011, and the SO was issued on 19 April 2013 and a supplementary SO, addressing in particular the IVAX Agreement, was issued on 21 October 2014. On 30 June 2015 the CMA issued a proposed "no grounds for action" ("NGFA") decision regarding the IVAX Agreement. The Appellants were able to put in full representations in response to each of these documents, and most did so. As we noted at the outset, the Decision itself was adopted on 12 February 2016, and at the same time the CMA issued a final NGFA decision regarding the IVAX Agreement.

435. There can be no doubt that the Decision, and indeed the start of the investigation, came a long time after the events on which the Decision is founded. The CMA's explanation is that the potential infringements were brought to the attention of the UK competition authority (then, the OFT) in 2010 by the Commission as a result of its inquiry into the pharmaceutical sector: Decision, para 2.1, and see paras 57-58 above.

436. Although there is no statutory limitation period within which the CMA must either commence or conclude an infringement action, GUK and Actavis argued that the passage of time compromised their ability to defend themselves as all of the key personnel involved in the commercial decision-making and negotiation of their respective Agreements had departed by the time of the investigation. All three Appellants raising this ground also argued that the passage of time meant that potentially exculpatory documents may no longer be available to them.

437. Although some of the Appellants criticised the CMA's explanation for the extensive delay before the start of the investigation, it is not relevant to this head of appeal to determine whether that explanation is satisfactory. The relevant question is whether the delay has compromised the rights of the

defence. In that regard, it is established that the burden of proving that delay has compromised the rights of defence lies with the appellant, who must show that the content of the decision would probably have been different but for the delay. Thus the General Court stated in Case T-27/10 *AC Treuhand v Commission* EU:T:2014:59, para 204:

> "[T]here is no need to annul a Commission decision, even where the procedure has been excessively long, where it has not been shown in detail that the rights of defence of the undertakings concerned have been impaired and there is thus no reason to believe that the excessive length of the procedure had an impact on the content of the Commission's decision."

438. In our view, the Appellants have not identified any witnesses or documentary evidence which would have affected the content of the Decision or the outcome of these appeal proceedings. We consider that the documentary record was sufficiently continuous and comprehensive to provide a clear explanation of the Appellants' motivations and negotiating stance. We note that Merck relied on the fact that it sold its interest in GUK in 2007 and retained only a limited number of documents, whereas GUK contended that as a result of that sale it no longer had access to documents which continue to be held by Merck. However, the allegations against GUK and Merck are co-extensive, in that Merck is liable only for the conduct of GUK, by reason of the decisive influence which it exercised over GUK at the time. Accordingly, GUK and Merck together would have every incentive to put forward all documents that might assist in defeating those allegations. As regards Actavis, it relied in particular on the fact that a warehouse where many documents relating to the Alpharma patent litigation were stored had been destroyed by fire. But that fire occurred in mid-2006, and we do not see that if the investigation had started only at the end of 2006 there could have been any complaint about delay, so that in any event it is only prejudice arising from delay thereafter which can be material.

439. As regards witnesses, although Mr Urwin may no longer have been in GUK's employment, GUK evidently was able to contact him as it submitted a full witness statement from him in 2013. Further, the OFT was able to interview not only Mr Urwin but also Mr Rosenberg. Neither GUK nor Actavis was

able to suggest, when specifically asked by the Tribunal, that it was unable to contact relevant witnesses: see further para 72 above.

440. As regards GUK's distinct argument that the CMA should have issued a further supplementary SO, despite bearing the burden of proof on that point GUK did not seek to develop that contention during the hearing. GUK's main submission under this challenge was that between the SO and the Decision, the CMA had changed its analysis of the IVAX Agreement and decided not to assert that it infringed competition law. GUK argued that the IVAX Agreement formed an important part of the relevant factual and economic context in which GUK agreed to settle the patent proceedings. However, following the first SO (and the supplementary SO), the CMA had issued the proposed NGFA decision concerning the IVAX Agreement and also three Letters of Facts relating to the new evidence upon which the CMA wished to rely, in response to each of which GUK had been able to make representations. As regards GUK's two other points, as the CMA's Defence makes clear, the CMA's approach in the revised pricing analysis was explained in the First Letter of Facts; and the change in emphasis placed on the Drug Tariff in our view does not come close to constituting a material change in the nature of the allegations such as would require a supplementary SO. Altogether, GUK has not shown why the SO, read together with the proposed NGFA decision and Letters of Facts, did not sufficiently alert it to the case against it. Moreover, we note that none of the other Appellants apparently had any difficulty understanding the case against them.

441. We therefore dismiss the arguments of GUK, Merck and Actavis that their rights of defence were infringed.

I. ATTRIBUTION OF JOINT AND SEVERAL LIABILITY TO XELLIA AND ALLC

442. By ground 4 of Xellia and ALLC's joint notice of appeal, they argued that the CMA erred in holding them jointly and severally liable with Actavis for the infringement of the Chapter I prohibition that resulted from the Alpharma Agreement.

443. In the Decision, the CMA attributed liability for the making of the Alpharma Agreement, and therefore the infringement of the Chapter I prohibition, to:

(1) Actavis, which was then (i.e. at the date of the Alpharma Agreement) known as Alpharma Ltd;

(2) Xellia, which was then known as Alpharma ApS; and

(3) ALLC, which is the functional and economic successor to the company then known as Alpharma Inc.

444. The CMA attributed liability to Actavis on the basis that it was the legal entity which had entered into the Alpharma Agreement. This attribution was undisputed.

445. The CMA attributed liability to Xellia and ALLC on two bases:

(1) that Xellia and ALLC were directly involved in the infringement, through their employees; and

(2) that Xellia and ALLC exercised decisive influence over Actavis at the time of the infringement since Xellia was the 100% indirect parent company of Actavis, and ALLC was the 100% indirect parent company of Xellia; and no evidence was provided to rebut the presumption that a 100% parent company exercises decisive influence over its subsidiaries.

446. Xellia and ALLC attacked the CMA's attribution of liability, arguing that:

(1) the CMA should have attributed liability to another company, A. L. Industrier ASA, since it was the ultimate parent company of the group and in fact exercised decisive influence over Alpharma Inc. Therefore, it was discriminatory on the part of the CMA to select intermediate companies (i.e. Xellia and ALLC) while ignoring their parent; and

(2) the attribution of liability through their employees' direct involvement in the infringement was "weak".

447. Before considering the substance of these arguments, we note that the two forms of attribution of liability relied on in the Decision are alternatives. Therefore, if we are satisfied that Xellia and ALLC were directly involved in the infringement, there is no need to consider the CMA's secondary method of attribution (decisive influence) and the contention of discrimination.

448. In our view, the evidence overwhelmingly demonstrates the direct involvement of Xellia and ALLC, through their senior executives, in the making of the Alpharma Agreement. It is not in dispute that Mr Laursen (of Alpharma ApS, now Xellia) and Mr Magrab (of Alpharma Inc, now ALLC) were deeply involved in negotiating the Alpharma Agreement. Indeed, these two individuals were the representatives at the final meeting at which the deal with GSK was concluded: see para 128 above. The Decision also quotes the minutes of the committee of the Board of Alpharma Inc, formally approving the Alpharma Agreement: para 9.48.

449. Although it was not abandoned, Mr O'Donoghue very properly did not press this ground of appeal when questioned by the Tribunal during oral closing submissions. We consider that it is clearly without merit.

J. PENALTIES

450. All the Appellants challenged the respective penalty imposed on them. They contended that any violation was not "intentional or negligent" so that the statutory basis for a penalty was not satisfied, or alternatively that the level of penalty was excessive and/or disproportionate.

451. Although we heard argument on these grounds of appeal, since we are referring various questions to the CJEU for a preliminary ruling, we have in the end concluded that it would be inappropriate to determine these grounds in advance of the judgment of the CJEU. The answers to the various questions submitted may well affect the question of penalties, and we will therefore

determine the grounds of appeal relating to penalties after the ruling of the CJEU, on which the parties will have the opportunity to make further submissions.

K. CONCLUSION

452. For the reasons set out above, we therefore:

(1) dismiss ground 2 of GSK's appeal, ground 4 of GUK's appeal, ground 3 of Actavis' appeal and ground 3 of the Xellia/ALLC joint appeal regarding the application of the Exclusion Order;

(2) dismiss ground 5 of GSK's appeal regarding the application of the VBER or that the GUK and Alpharma Agreements are entitled to individual exemption;

(3) dismiss ground 5 of GUK's appeal, ground 3 of Merck's appeal and ground 4 of Actavis' appeal regarding infringement of the rights of defence; and

(4) dismiss ground 4 of the Xellia/ALLC joint appeal regarding the attribution to them of liability for the Alpharma Agreement.

453. As explained above, we shall refer to the CJEU under Art 267 TFEU for a preliminary ruling specific questions concerning the interpretation of Art 101 as regards potential competitors, the object of the GUK and Alpharma Agreements, and the effect of the GUK and Alpharma Agreements; and specific questions concerning the interpretation of Art 102 as regards the definition of the market in the context of the abuse here alleged and as regards the question of abuse including the relevance of the benefit to the NHS resulting from the IVAX Agreement. We are circulating draft questions accordingly to the parties for comment together with the delivery of this judgment.

454. This judgment is unanimous.

Mr Justice Roth
President

Dermot Glynn

Hodge Malek QC

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

Date: 08 March 2018

APPENDIX

CHRONOLOGY: AGREEMENTS AND LITIGATION

Date	Event	Para
January 1999	Patent protection on the paroxetine hydrochloride molecule ends	9
December 2000	Data exclusivity ends	9
27 July 2001	BASF commences revocation proceedings against GSK's Anhydrate patent	27
18 September 2001	GSK commences infringement proceedings against GUK under the Anhydrate patent	27
3 October 2001	IVAX Agreement (12 month initial term) and side letter	22; 24
23 October 2001	Jacob J grants interim injunction against GUK	28
4 December 2001	GSK commences infringement proceedings against GUK under the Hemihydrate patent. Court directs that the BASF revocation proceedings and GUK infringement proceedings (both concerning the Anhydrate patent) be heard together.	31
15 February 2002	1st Addendum to IVAX Agreement (two year extension)	26
13 March 2002	GUK Agreement	32
14 March 2002	IVAX-GUK Supply Agreement; GSK and IVAX Heads of Agreement; BASF trial starts	34; 35; 36
11 June 2002	GSK starts infringement proceedings against Alpharma under both the Anhydrate and Hemihydrate patents	37
24 June 2002	Alpharma gives undertaking to court pending BASF judgment	37
12 July 2002	Pumfrey J judgment in BASF litigation	36
1 August 2002	GSK amends claim against Alpharma, dropping Hemihydrate patent from the proceedings	116
1 August 2002	Alpharma extends duration of its undertaking to the court	37
12 September 2002	2nd Addendum to the IVAX Agreement	35
October 2002	GSK commences proceedings against Apotex under the Anhydrate patent	40
12 November 2002	Alpharma Agreement	41
20 November 2002	IVAX-Alpharma Supply Agreement; 3rd Addendum to the IVAX Agreement	42; 44
28 November 2002	Jacob J grants interim injunction against Apotex	47
December 2002	Date listed for Alpharma trial (n.b. listing vacated following signing of Alpharma Agreement on 12	37

	November 2012)	
25 June 2003	Court of Appeal judgment in the BASF litigation Apotex trial starts	36; 48
14 November 2003	Alpharma Amendment Agreement	45
5 December 2003	Pumfrey J judgment in the Apotex litigation	48
18 December 2003	Interim injunction against Apotex discharged	48
13 February 2004	Alpharma Agreement and IVAX Alpharma Supply Agreement terminated	51
25 June 2004	IVAX-GUK Supply Agreement terminated	52
29 June 2004	IVAX Agreement terminated	53
1 July 2004	GUK Agreement terminated	52
29 November 2004	Court of Appeal judgment in the Apotex litigation	48