IN THE COMPETITION APPEAL TRIBUNAL

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

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

ORDER FOR REFERENCE FOR A PRELIMINARY RULING

HAVING REGARD TO the Tribunal's judgment in these proceedings of 8 March 2018 ([2018] CAT 4) (the "**Judgment**") in which the Tribunal decided to refer certain questions to the Court of Justice of the European Union ("**CJEU**") for a preliminary ruling

AND HAVING REGARD TO rules 19(2)(m) and (n), 107(1), and 109 of the Competition Appeal Tribunal Rules 2015 (2015 S.I. 1648) and Article 267 of the Treaty on the Functioning of the European Union

IT IS ORDERED THAT:

1. The questions in Schedule 1 with the accompanying Statement of Facts in Schedule 2 are referred to the CJEU for a preliminary ruling.

2. Pending the delivery of the CJEU's preliminary ruling these proceedings are stayed.

3. Time to request permission to appeal the Judgment is extended until three weeks after the Tribunal's final decision in the appeals which will follow the CJEU's preliminary ruling and any further submissions thereafter.

Mr Justice Roth
President

Dermot Glynn

Hodge Malek QC

Made: 27 March 2017
Drawn: 27 March 2017

Schedule 1

QUESTIONS

The Tribunal refers to the Court of Justice of the European Union pursuant to Article 267 of the Treaty on the Functioning of the European Union ("TFEU") the following questions which arise in these joined appeals under the UK domestic equivalents to Articles 101 and 102 TFEU (and to a limited extent also directly under Article 101). Since the UK provisions are to be interpreted consistently with Articles 101 and 102 the questions are framed by reference to those provisions of the TFEU.

Potential competition

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

2. Does the answer to Question 1 differ if:
   (a) there are pending court proceedings between the parties involving this dispute; and/or
   (b) the patent-holder has obtained an interim injunction preventing the generic company from launching its generic product on the market until determination of those proceedings; and/or
   (c) the patent holder regards the generic company as a potential competitor?

Restriction by object

3. When there are pending court proceedings concerning the validity of a patent for a pharmaceutical drug and whether a generic product infringes that patent, and it is not possible to determine the likelihood of either party succeeding in those proceedings, is there a restriction of competition "by object" for the purpose of Article 101(1) when the parties make an agreement to settle that litigation whereby:
   (a) the generic company agrees not to enter the market with its generic product and not to continue its challenge to the patent for the duration of the agreement (which is no longer than the unexpired period of the patent), and
   (b) the patent holder agrees to make a transfer of value to the generic company in an amount substantially greater than the avoided litigation costs (including management time and disruption) and which does not constitute payment for any goods or services supplied to the patent holder?

4. Does the answer to Question 3 differ if:
   (a) the scope of the restriction on the generic company does not go beyond the scope of the patent in dispute; and/or
   (b) the amount of the value transfer to the generic company may be less than the profit it would have made if it had instead succeeded in the patent litigation and entered the market with an independent generic product?

5. Do the answers to Questions 3 and 4 differ if the agreement provides for the supply by the patent holder to the generic company of significant but limited volumes of authorised generic product and that agreement:
   (a) does not give rise to any meaningful competitive constraint on the prices charged by the patent holder; but
   (b) brings some benefits to consumers which would not have occurred if the patent holder had succeeded in the litigation, but which are significantly less than the full competitive benefits resulting from independent generic entry which would have occurred if the generic company had succeeded in the litigation, or is this relevant only to assessment under Article 101(3)?

Restriction by effect

6. In the circumstances set out in Questions 3-5, is there a restriction of competition "by effect" for the purpose of Article 101(1) or does that depend upon the court finding that in the absence of that settlement:
   (a) the generic company would probably have succeeded in the patent proceedings (i.e. that the chance that the patent was valid and infringed was below 50%); alternatively
   (b) the parties would probably have entered into a less restrictive settlement (i.e. that the chance of a less restrictive settlement was above 50%)?

Market definition

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

Abuse

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

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

10. Does the answer to Question 8 or 9 differ if:
    (a) the patent holder pursues a strategy of entering into several such agreements to preclude the risk of unrestricted generic entry; and
    (b) the consequence of the first such agreement is that by reason of the structure of the national arrangements for reimbursement by the public health authorities to pharmacies of their costs of purchasing pharmaceutical drugs, the reimbursement level for the pharmaceutical drug in question is reduced, resulting in a substantial saving to the public health authorities (albeit a saving which is significantly less than that which would arise upon independent generic entry following a successful outcome for the generic company in patent litigation); and
    (c) that saving was no part of the intention of the parties when entering into any of the agreements?

Schedule 2

STATEMENT OF FACTS

Contents

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"). These provisions are the domestic equivalents of Art 101 Treaty on the Functioning of the European Union ("TFEU") and Art 102 TFEU respectively. 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 TFEU when applying the equivalent provision of domestic law, the parties to that agreement were also found to have infringed Art 101 TFEU 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. Each of the Agreements was made between GSK[1] 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 Patents Court of England and Wales, 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. A schedule setting out a chronology concerning the Agreements and various patent actions referred to below is in **Appendix 1**.

5. The judgment of the Tribunal ("the Judgment"), from which this Statement of Facts is derived but which covers also other matters argued by the parties which are not relevant to this reference, is in **Appendix 2**. The Judgment also includes discussion of the decisional practice of the European Commission ("Commission") and

[1] Some of the agreements were made by GSK's subsidiary, SmithKline Beecham plc, but there is no need to distinguish between them and, for convenience, the companies will be referred to without distinction as "GSK".

jurisprudence of the Court of Justice of the European Union ("CJEU") and, having regard to para 23 of the CJEU's Information Note on references from national courts for a preliminary ruling (OJ 2009 C 297), the Judgment sets out the Tribunal's provisional views on most of the questions referred for a preliminary ruling, as cross-referenced below.

B. THE FACTS

(1) Paroxetine

6. 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[2], which over the relevant period was one of GSK's highest selling products, both in the UK and world-wide.

7. 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. Patent protection for the paroxetine hydrochloride molecule (the active pharmaceutical ingredient or "API") expired in January 1999 and GSK's right to data exclusivity[3] expired in December 2000.

8. By that time, GSK had obtained a number of further "secondary" patents. For the purpose of this reference, the relevant secondary patent was GB 2 297 550 (the "Anhydrate Patent"), which covers four polymorphs of paroxetine hydrochloride anhydrate and the process to produce them. The Anhydrate Patent 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]

9. Over the relevant period, GSK produced Seroxat in two doses: 20mg and 30mg. The 20mg dose was much the more significant: nevertheless, expenditure by the UK National Health Service ("NHS") on 30mg paroxetine accounted for about 27% of total NHS expenditure on paroxetine in 2001-02.

10. 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'.

11. 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

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[2] A blockbuster medicine has been defined by the Commission as a medicine of which the annual global turnover exceeds $1 billion: Decision, fn 210.
[3] See para 12 below.
[4] In fact, the Anhydrate Patent expired in 2013 due to non-payment of renewal fees.

these opportunities. As at September 2001, PIs accounted for approximately 30-40% (by volume) of paroxetine dispensed in the UK. However, PIs came only for the 20mg dosage of paroxetine; there were no PIs of the 30mg tablets.

12. 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 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).

13. For Seroxat, after the expiry on 10 December 2000 of its data exclusivity, GSK faced the possibility of generic suppliers seeking a MA under the abridged procedure to enter the UK market. 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, GSK could prevent such generic entry only if it could successfully rely on one or more of its secondary patents.

14. By about mid-2000 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"). GUK obtained a MA for paroxetine in Denmark in April 2001. Alpharma submitted an application for a MA in the UK on 30 May 2001.

(2) The IVAX Agreement

15. GSK and IVAX entered into the IVAX Agreement 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. Further it was agreed that:

    (1) The supply price (i.e. the price at which GSK would supply the Product to IVAX) was £8.45 per pack.

(2) 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 that IVAX had an immediate right to terminate if a generic product containing paroxetine hydrochloride as its active substance became available for £8.45 or below for three consecutive days.

(3) GSK would transfer to IVAX a "promotional allowance" of £3.2 million over the 12 month period (even if the agreement was terminated earlier under clase 3.2) (clause 5).

(4) Supply of the authorised generic paroxetine would be capped to a maximum volume of 770,000 packs (clause 7.3).

16. 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.

17. Over the period while the discussions with IVAX were taking place, litigation with other parties concerning GSK's Anhydrate Patent started in the Patents Court. On 27 July 2001, BASF commenced revocation proceedings against certain claims in the Anhydrate Patent. And 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 proceedings against GUK and the GUK Agreement

18. GSK sought interim relief against GUK and on 23 October 2001, the Court granted an interim injunction against GUK entering the market and GSK gave a cross-undertaking in damages.[5] On 4 December 2001, the Court directed that the BASF case and the GUK case, which both concerned the Anhydrate Patent, should be heard together the following March.

19. 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 were discharged, all claims to damages were waived, 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.

[5] 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.

(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 (see para 21 below).

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

20. 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.

21. 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 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 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[6] 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."

22. GSK and IVAX at the same time agreed to amend the IVAX Agreement, on terms formally set out in a 2nd Addendum signed on 12 September 2002. This extended the term of the IVAX Agreement to 13 March 2005 (thereby 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. Under the 2nd Addendum GSK also 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.

[6] 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.

(4) The BASF Trial

23. The trial of the BASF action commenced on 14 March 2002, obviously without the participation of GUK. Judgment was given on 12 July 2002, holding that most of the product claims in the Anhydrate Patent were invalid, but that two of the process claims were valid.

(5) The Proceedings against Alpharma and the Alpharma Agreement

24. In the meantime, on 29 April 2002 Alpharma obtained a MA in the UK for paroxetine. On 11 June 2002, GSK started infringement proceedings against Alpharma, relying (insofar as relevant to this reference) on the Anhydrate Patent. GSK also sought interim relief and when the judge indicated that this was likely to be granted, on 1 August 2002 Alpharma gave an undertaking to the Court (of equivalent effect to an injunction) that it would not sell paroxetine in the UK until judgment and GSK gave a cross-undertaking in damages. Following the judgment in the BASF case, the only issue in the Alpharma case was infringement, and on that basis a short trial was listed to take place in December 2002.

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

26. 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.

27. 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 20mg paroxetine tablets 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."

28. Clause 11.3 of the IVAX-Alpharma Supply Agreement further provided that for up to two months following service of such notice to terminate if 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).

29. 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 GSK would reimburse IVAX for any liability it might have under cl. 11.3 of the IVAX-Alpharma Supply Agreement.

30. 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 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.

(6) The Apotex Judgments

31. On 28 November 2002, the Court had granted an interim injunction restraining Apotex, Neolab and Waymade from selling its paroxetine on the UK market.

32. On 25 June 2003, the trial of the Apotex litigation commenced. On 5 December, the Court gave judgment holding that the remaining claims (i.e. those which had not been invalidated in the BASF judgment: para 23 above) were plainly not infringed by the process used by Apotex. Although GSK appealed, it did not seek to renew the injunction pending the appeal and the injunction was accordingly discharged on 18 December 2003. (The Court of Appeal eventually upheld the judge's decision that there was no infringement.)

33. 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. The Decision, and also the appeals, proceeded on the basis that it was impossible to determine the likelihood of either GSK on the one hand, or GUK/Alpharma on the other hand, being successful in the litigation if those cases had gone to trial. Similarly, it is uncertain whether GSK could have successfully relied on its patents to prevent the launch of a generic product by IVAX.

(7) Independent generic entry and the effect on price

34. Following the judgment in the Apotex litigation and GSK's decision not to seek a further injunction, Neolab and Waymade entered the market in late December 2003 as distributors for Apotex with a 20 mg product. The market was now effectively open.

35. On 13 January 2004, Alpharma gave IVAX one month's notice to terminate the IVAX-Alpharma Supply Agreement pursuant to clause 11.3; para 27 above. That had the effect of similarly ending the restriction on Alpharma under the Alpharma Agreement: para 26(6) above. In February 2004, Alpharma entered the market with its own, independently sourced paroxetine.

36. 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 21 above. Termination of the IVAX-GUK Supply Agreement ended 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.

37. 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.

38. None of the agreements discussed above involved supply of the more expensive, but less frequently prescribed, 30mg paroxetine. In February 2004 Alpharma was the first generic company to launch a 30mg product.

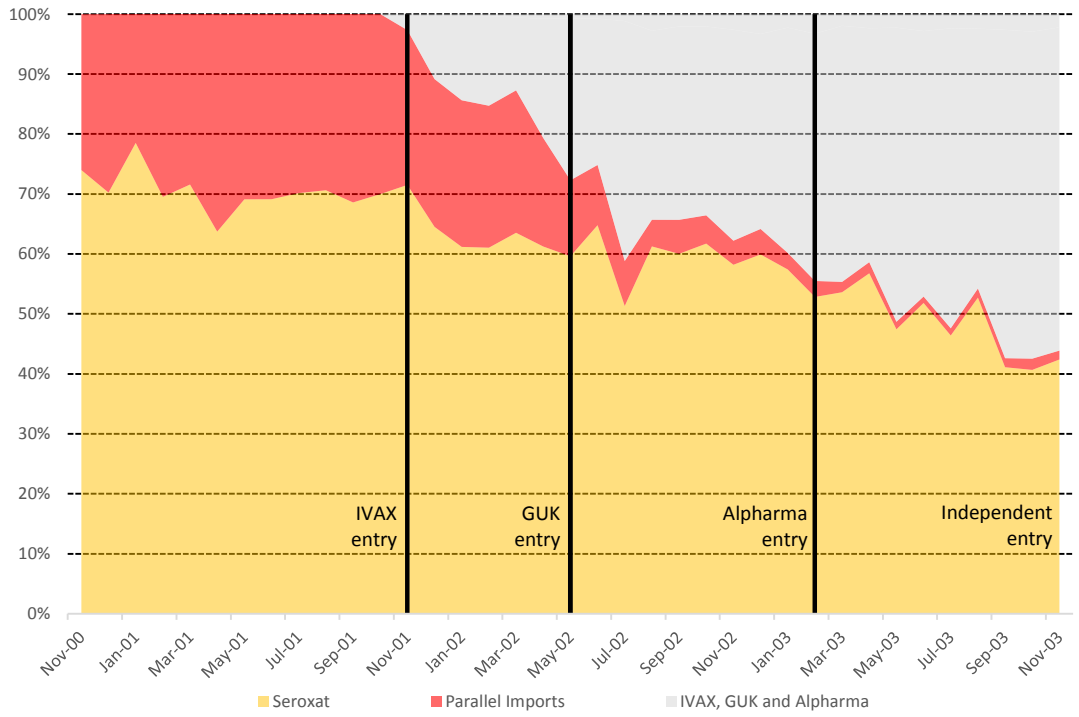
39. The effect on prices of independent generic entry was dramatic. The Decision records that for 20mg paroxetine, in the first three months following generic entry in December 2003, prices fell by 34%; and that they had fallen by 69% one year later (representing a fall from £12.95 to £3.97 per pack over the year). For 30mg paroxetine, the price had fallen by around 66% by December 2005. Average paroxetine prices (for both 20mg and 30mg) had fallen by around 74% by December 2005.

40. In summary, the Agreements between GSK and the generic companies IVAX, GUK, and Alpharma avoided (in the case of IVAX) or ended (in the case of GUK and Alpharma) 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.

41. 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 the graph below: it can be seen that between November 2001 and November 2003 the market share of generics from IVAX, GUK and Alpharma grew by almost 60 percentage points, displacing almost all PIs (some 30 percentage points) and Seroxat (another almost 30 percentage points.) The Agreements had no impact on the sales by GSK of 30 mg paroxetine.

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



C. THE DECISION

42. On 12 February 2016, the CMA concluded that there were no grounds for action regarding the IVAX Agreement,[7] and adopted the Decision. Under the Decision, the CMA found that:

[7] The CMA decided that the IVAX Agreement was excluded from the domestic equivalent of Article 101 TFEU under a domestic legislative provision which was applicable at the relevant time but which was later repealed.

(1) GSK held a dominant position in the market for paroxetine and had abused that position contrary to the Chapter II prohibition by entering into the IVAX, GUK and Alpharma Agreements.

(2) GSK and GUK (and its parent Merck) had infringed the Chapter I prohibition and (after 1 May 2004) Article 101 TFEU by entering into the GUK Agreement.

(3) GSK and the Alpharma companies (Actavis, Xellia and ALLC) had infringed the Chapter I prohibition by entering into the Alpharma Agreement.

43. The CMA also determined that the addressees of the Decision should pay financial penalties for the particular infringement for which they were found liable.

D. THE APPEALS

(1) Potential competition: Reference Questions 1-2

44. GSK and the generic companies (together the "Appellants") appealed the findings in the Decision that GUK and Alpharma were potential competitors of GSK. They argued that as they were not potential competitors there was no infringement of the Chapter I prohibition (or Art 101 TFEU).

45. In the provisional view of the Tribunal, GUK and Alpharma are properly to be regarded as potential competitors with GSK, notwithstanding the existence of the interim injunctions against those companies: paras 136-143 of the Judgment. The Tribunal further considered that this conclusion is consistent with the judgments of the General Court in the *Lundbeck* cases[8]: paras 144-159 of the Judgment.

Further findings relevant to potential competition

(a) GUK

46. GUK had both the ability and firm intention to enter the market, and would have done so 'at risk' if GSK had not obtained the interim injunction against it. GUK had made considerable investments acquiring significant stocks of generic paroxetine in preparation for launch of its product and had actively sought customers prior to the grant of the interim injunction. Before GSK commenced proceedings, GUK had taken orders for about 0.5 million packs of paroxetine, amounting to about £5.5 million.

47. Although the grant of the interim injunction was unexpected in the light of the previous approach of the courts in such cases, it did not materially affect GUK's confidence in its prospects in its case against GSK. Had GSK not presented to GUK a sufficiently attractive deal, GUK would have pressed on to trial.

48. Further, the duration of the GUK Agreement (three years) significantly exceeded the period of restraint under the interim injunction. The period of restraint under the

[8] 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.

interim injunction until first instance judgment would have been four months, and if it had been extended for the duration of an appeal it would have been continued for perhaps an additional period of some six months.

(b) Alpharma

49. At the start of the infringement proceedings Alpharma, unlike GUK, would not have launched 'at risk' of infringement of the Anhydrate Patent.

50. In the early stages of the litigation, therefore, the interim restraint only prevented Alpharma from doing what it was not prepared to do anyway. However, by late July 2002, following the outcome of the BASF trial, Alpharma probably would have been prepared to launch 'at risk' since it was relatively confident that its product did not infringe the Anhydrate Patent. Alpharma was thus concerned and frustrated by the prospect of even a relatively short delay.

51. As with GUK, had GSK not presented to Alpharma a sufficiently attractive deal, Alpharma would have pressed on to trial. A trial would have taken place in December 2002 and a first instance judgment would have been expected in about January 2003. If GSK had lost at first instance, it probably would have appealed. But if an interim restraint on Alpharma had continued pending an appeal, then the appeal would probably have been expedited and a judgment would have been rendered in about six months (i.e. by about July 2003). By contrast, the Alpharma Agreement was for a one year term to 30 November 2003, subsequently extended by a further year to 30 November 2004. Thus the exclusion of Alpharma as a supplier of independent generic paroxetine under the Alpharma Agreement lasted considerably longer than any potential interim relief.

52. In short, if the parties had not successfully come to terms and Alpharma had prevailed in the litigation, it would have launched its product in the UK, for which it had the necessary arrangements for production.

(c) GSK

53. GSK regarded GUK and Alpharma as potential competitors. This is why it sought interim injunctions to prevent their launching generic paroxetine in the UK. In its evidence to the Patents Court in support of its applications for those injunctions, GSK stressed the likelihood of generic companies seeking to enter this valuable market and the dramatic effect which such entry would have on the pricing structure of paroxetine. This is also why the GUK and Alpharma Agreements each contained provisions precluding the generic company from entering the UK market.

54. However, if GSK was correct in its contentions in the respective litigation against GUK and Alpharma, which never came to trial, then entry by GUK or Alpharma would have been unlawful. Further, while the interim restraints on GUK and Alpharma were in place, the respective generic company could not enter the market.

(2) <u>Restriction "by object": Reference Questions 3-5</u>

55. The Appellants appealed the finding in the Decision that the Agreements infringed the Chapter I prohibition 'by object'. The Tribunal discusses the relevant parts of the Decision and the parties' arguments contesting this conclusion at, respectively, paras

160 to 164 and 274 to 308 of the Judgment. The significance in this regard of the judgments of the General Court in *Lundbeck* are addressed at paras 309 to 319 of the Judgment. The Tribunal sets out its provisional views relevant to these questions at paras 320 to 326 of the Judgment.

Further findings relevant to restriction "by object"

(a) The terms of the Agreements

56. The material terms of the GUK and the Alpharma Agreements, and the related Supply Agreements with IVAX, are summarised above. We draw attention to several aspects of those two Agreements, some of which are pertinent also to the IVAX Agreement.

57. *Volumes of paroxetine supplied:* 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, that was achieved by way of GSK supplying those additional quantities to IVAX, which IVAX in turn supplied to GUK and Alpharma. There were no technical reasons which would have prevented the supply of greater volumes than the capped volumes under each of the Agreements.

58. *"Marketing Allowance"*: 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 months 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. However, these sums were not related to any expected marketing expenditure. This applies also to the so-called "promotional allowance" of £3.2 million which GSK agreed to pay IVAX under clause 5 of the IVAX Agreement. The labels "Marketing Allowance" and "Promotional Allowance" applied to these sums were misleading.

59. *The values transferred:* GSK effectively undertook to make a value transfer to GUK of £21.3 million over the three year term. This transfer was made partly in cash and partly through a distribution margin on the supplied volumes of generic paroxetine. Similarly, GSK effectively undertook to make a value transfer to Alpharma of about £10 million over the two years. Again, this transfer was made partly in cash and partly through a distribution margin on the supplied volumes of generic paroxetine. In both instances, the values transferred 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. Further, GUK received a guarantee of its profit margin from GSK, which undertook to make up the shortfall in the event that GUK's selling price fell below a certain level. Alpharma did not receive an equivalent guarantee but had the right to terminate its arrangements in the event of independent generic entry onto the market and received a profit guarantee for the two months following termination.

60. *Restrictions on entry:* Both the GUK and Alpharma Agreements precluded the generic company from independent entry into the UK market, i.e. with its own

generic product. That restriction was imposed through each company's linked Supply Agreement with IVAX.

61. *Settlement of the patent proceedings:* Both the GUK and Alpharma Agreements were made in settlement of the pending patent actions between the generic company and GSK. However, 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. The duration of each Agreement was significantly less than the unexpired term of the Anhydrate Patent.

(b) The strength of the Anhydrate Patent

62. As regards the subjective views of the parties, while GUK and Alpharma were of course aware of the risks of litigation, neither believed that it was likely to lose and settled on the basis of weakness. Similarly, there is no basis for finding that GSK expected to lose either of the two cases although we found that it was not altogether confident that it would succeed. None of the parties disclosed the legal advice it had received in the patent proceedings.

63. As regards the objective position, it is impossible for the Tribunal to determine on the evidence the likelihood of either GSK or the generic company succeeding if their respective cases had gone to trial.

(c) Subjective intention of the parties

64. GSK's intention was to settle the patent disputes and maintain the integrity of its patents. The Agreements served to avoid the risk that the Anhydrate Patent would be invalidated or found not to be infringed. From GSK's perspective, the Agreements were not ideal but they served to maintain stability by ensuring what the then Finance Director of GSK's UK pharmaceutical business described as a "controlled scenario", as opposed to "full generic entry".

65. GSK had a European management team which directed overall strategy within Europe:

(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 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.

(5) 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, this was not the main reason for GSK deciding to enter into the Agreements.

66. GUK and Alpharma each entered into its respective Agreement because it considered that the terms 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.

(d) Settlement of litigation

67. The GUK and Alpharma Agreements were made in settlement of litigation. Two alternative forms of settlement agreement were discussed during the trial: (i) a patent licence in return for royalty payments; and (ii) an 'early entry' agreement, whereby the generic company was granted a right to enter before the expiry of the patent period.

68. It is impossible to say whether such an alternative form of settlement might have been practicable in the circumstances of this case. It is possible that the parties may have entered into such alternative agreements if a value transfer had not been permitted; but equally the parties may have fought the cases to the end.

(e) The supply arrangements

69. Overall demand for paroxetine is inelastic, i.e. it does not vary significantly according to changes in price. At the relevant time, doctors in their prescribing decisions took little or no account of price. GSK faced competition from PIs on 20mg Seroxat (but not on 30mg Seroxat). PIs were sold both 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 very significant. The PI price at the time was about £13 compared to GSK's list price of £17.76.

70. 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 in return for a commitment to purchase only UK-originated Seroxat.

71. 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 around the prevailing PI price. 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. PI volumes fell significantly on the entry of IVAX into the market in December 2001 following the IVAX Agreement, and declined to a minimal level following further volumes supplied by GUK following the GUK Agreement in mid-March 2002: see graph at para 41 above.

72. Since paroxetine was a prescription-only drug, the effective payment on behalf of patients was made by the NHS through a reimbursement scheme to pharmacies. The patients and the NHS can therefore both be regarded as the final consumers, and the price paid by the NHS was effectively the consumer price.

73. The NHS reimbursement scheme at the time operated according to the NHS Drug Tariff (the "Drug Tariff"). The Drug Tariff comprised various categories and each drug was placed in a particular category. 20 mg 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. For Category C drugs, pharmacies were reimbursed according to the originator's List Price. For Category A drugs, the reimbursement was calculated as a weighted average of the price lists of certain wholesalers and generics suppliers.

74. The volume of PIs meant that the *average* price paid by pharmacies for 20mg paroxetine was significantly less than the GSK List Price, as a result of a combination of PI purchases and the GSK brand equalisation 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. Therefore reimbursement to pharmacies under the Drug Tariff for paroxetine while it was in Category C gave pharmacies the benefit of a retained profit that was larger than it would have been in the absence of PIs, or if the Drug Tariff had treated PIs in a similar way to generic supplies. There was a complex adjustment mechanism applied periodically in an attempt to take account of this, but it was not perfect.

75. The introduction of authorised generic supply pursuant to the IVAX Agreement 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.

76. The reclassification under the Drug Tariff therefore led to a reallocation of monies as between pharmacies and the NHS, reducing the retained profit enjoyed by pharmacies, to the significant benefit of consumers. This was despite the fact that the new generic supplies were limited in volume and sold at similar prices to PIs of the same drug. There was no suggestion 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 the companies involved would have been very familiar with the Drug Tariff regime. In any event, this saving was directly attributable to the IVAX Agreement and not to the GUK and Alpharma Agreements.

77. The displacement of PIs by the authorised generic supplies brought some limited competitive benefit to consumers in quality terms, since PIs were less favoured by patients and pharmacies. Although the pharmaceutical product was physically the same, consumers were not attracted by the over-stickering of foreign language packaging of the PIs, and pharmacies favoured the security of supply which the generic companies could offer.

78. The generic companies (IVAX, GUK and Alpharma) were principally selling their authorised supplies of paroxetine to wholesalers, and the wholesalers in turn sold to

pharmacies. Because of the limited volumes supplied, the generic companies were not competing with each other in any meaningful sense in their sales to wholesalers, and the wholesalers were not competing in any meaningful sense in their sales to pharmacies.

79. The Tribunal found that the Agreements did not give rise to any meaningful competitive constraint on GSK. Although the market share of Seroxat was obviously reduced as a result of the Agreements, the supply to the generic companies was not intended to introduce price competition with GSK, nor did it in fact do so. Accordingly, those supplies should be regarded as non-cash value transfers.

80. However, 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 41 above.[9] Hence the volumes of authorised generic supply pursuant to the Agreements meant that pharmacies reduced the share of their purchases accounted for by higher priced Seroxat. This reduction in price was difficult to estimate with accuracy due to problems with the data, but was certainly no more than 4% and possibly rather less. We concluded therefore that it was small but not insignificant.

81. This price reduction was the 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 list price. The resulting price reduction to pharmacies was the consequence of a significant change in the structure of the market engineered by GSK, and should not be regarded as resulting from genuine competition.

82. The benefits resulting from the supply arrangements under the Agreements, as set out above, were certain not potential. However, they are dwarfed by the effect that would flow from potential independent and unrestricted generic entry ("genericisation"), as indeed occurred from December 2003 (see para 34 above):

    (1) Genericisation brought a much greater fall in the price of 20 mg paroxetine than resulted from the Agreements: see para 39 above;

    (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: para 9 above.

(3) Restriction of competition "by effect": Reference Question 6

83. The Appellants appealed the finding in the Decision that the Agreements infringed the Chapter I prohibition 'by effect'. The Tribunal discusses the parties' arguments contesting this conclusion and regarding the Commission's decision in *Servier*[10] at paras 327 to 349 of the Judgment.

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

[10] Case AT.39612 – *Perindopril (Servier)*; on appeal before the General Court in 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*.

84. The Tribunal found that in the absence of the Agreements there was a real *possibility:*

(1) that the generic companies would have succeeded against GSK in the patent litigation: para 63 above; alternatively

(2) that the parties would have entered into a less restrictive form of settlement: paras 67-68 above.

However, if a determination that there is a restriction by effect requires a finding that it was more likely than not that the generic company would have succeeded in establishing the right to enter the market or that the parties would have entered into a less restrictive form of settlement, such a finding cannot be reached on the evidence in this case.

(4) Dominance and Market Definition: Reference Question 7

85. GSK appealed the finding in the Decision that GSK held a dominant position in the market for the paroxetine molecule in the UK. The parties agreed that the geographic market was the UK. GSK accepted that if the CMA had correctly defined the relevant product market as paroxetine, then it held a dominant position. However, GSK argued that the relevant product market was all SSRIs.[11] The CMA accepted that if the relevant product market comprised all SSRIs, then GSK did not hold a dominant position.

86. The Tribunal discusses the arguments of GSK and the CMA at paras 388 to 409 of the Judgment. The Tribunal decided that it is artificial to use a SSNIP test to determine the product market when the product is not price sensitive. In the provisional view of the Tribunal, definition of the market is to be considered in the context of the conduct alleged to constitute an abuse. Although for some purposes the relevant market may have comprised all SSRIs, since the conduct at issue is the exclusion of generic paroxetine at a time when generic companies were threatening to enter the market, then for the purpose of defining the market the generic products should be included: paras 395 and 402 of the Judgment. That provisional conclusion was supported by the competitive constraint exercised by PIs: para 407 of the Judgment.

Further findings relevant to market definition

87. Paroxetine belongs to the class of anti-depressants known as SSRIs which comprises a fourth level class under the Anatomical Therapeutical Chemical ("ATC") classification system. There were no significant therapeutic differences between paroxetine and other SSRIs. GSK marketing personnel viewed Lundbeck's Cipramil and Cipralex (both SSRIs) as the closest competitors to Seroxat and engaged in promotional and marketing efforts to meet the challenge it felt from, in particular, Cipramil and Cipralex.

[11] And low dose venlafaxine.

88. There was little effective price constraint from other SSRIs on the pricing of Seroxat by GSK. But that is the inevitable consequence of the lack of price sensitivity of prescription-only medicines on the UK market.

89. The degree of competition from alternative SSRIs pales into insignificance compared to the effect of independent generic paroxetine when it came onto the market from December 2003: see the effect on prices set out at para 39 above. Thus the competitive constraint on prices then exercised by the independent generic product far outweighs any pressure on GSK from other SSRIs, notwithstanding their therapeutic equivalence, but there was no independent generic product on the market at the time of the relevant conduct.

90. There was competitive pressure on GSK's prices from PIs of paroxetine. GSK responded by offering significant price discounts or rebates on 20mg Seroxat, through the 'brand equalisation' deals it concluded with pharmacies: paras 70-74 above. The extent of the rebate an individual pharmacy received reflected an assessment of the degree to which it would otherwise purchase PI product. GSK offered no such deals on the 30mg product, which did not face competition from PIs.

(5) Abuse: Reference Questions 8-10

91. GSK appealed the finding in the Decision that its conduct in entering the Agreements constituted an abuse of its dominant position. To a considerable extent whether or not this finding is correct depends on the answers to Reference Questions 3-5 (concerning whether the conduct constituted a 'by object' infringement). However, there is a factual difference since the alleged abuse covers also the IVAX Agreement, which brought about a substantial saving for consumers (the NHS): para 75 above. The Tribunal discusses the parties' arguments on this point at paras 419-425 of the Judgment.

Further findings relevant to abuse

92. GSK never started legal proceedings against IVAX although IVAX was able to source independent paroxetine. GSK regarded IVAX as a potential competitor at the time.

93. 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.

94. 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. This led directly to the reclassification of paroxetine under the Drug Tariff from June 2002. That in turn led to a significant saving for the NHS by reason of the significantly lower reimbursement price: see para 75 above. This self-evidently was a significant benefit for the NHS, although it did not produce the same savings that would result from unrestricted and independent generic entry that would have followed success by IVAX in the (hypothetical) patent proceedings.

95. 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), this was the intention and understanding of the parties.

96. 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 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.

97. 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. 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.

98. The entry into the IVAX Agreement was part of the overall strategy of GSK which led also to its subsequent entry into the GUK and Alpharma Agreements: para 65 above.

APPENDIX 1: CHRONOLOGY

Date	Event	Para
January 1999	Patent protection on the paroxetine hydrochloride molecule ends	7
December 2000	Data exclusivity ends	7
27 July 2001	BASF commences revocation proceedings in respect of GSK's Anhydrate patent	17
18 September 2001	GSK commences infringement proceedings against GUK under the Anhydrate patent	17
3 October 2001	IVAX Agreement (12 month initial term)	15
23 October 2001	Interim injunction against GUK	18
4 December 2001	Court directs that the BASF revocation proceedings and GUK infringement proceedings (both concerning the Anhydrate patent) be heard together.	18
15 February 2002	1st Addendum to IVAX Agreement (two year extension)	16
13 March 2002	GUK Agreement	19
14 March 2002	IVAX-GUK Supply Agreement; BASF trial starts	21; 23
11 June 2002	GSK starts infringement proceedings against Alpharma under the Anhydrate Patent	24
24 June 2002	Alpharma gives undertaking to court pending BASF judgment	24
12 July 2002	Judgment in BASF litigation	23
12 September 2002	2nd Addendum to the IVAX Agreement	22
October 2002	GSK commences proceedings against Apotex under the Anhydrate patent	25
12 November 2002	Alpharma Agreement	26
20 November 2002	IVAX-Alpharma Supply Agreement; 3rd Addendum to the IVAX Agreement	27; 29
28 November 2002	Interim injunction against Apotex	31
December 2002	Date listed for Alpharma trial (n.b. listing vacated following signing of Alpharma Agreement on 12 November 2012)	24
5 December 2003	Judgment in the Apotex litigation	32
18 December 2003	Interim injunction against Apotex discharged	32
December 2003	Neolab and Waymade enter the market as distributors for Apotex	34
13 February 2004	Alpharma Agreement and IVAX-Alpharma Supply Agreement terminated	35
25 June 2004	IVAX-GUK Supply Agreement terminated	36
29 June 2004	IVAX Agreement terminated	37
1 July 2004	GUK Agreement terminated	36

APPENDIX 2: JUDGMENT OF THE TRIBUNAL OF 8 MARCH 2018