Neutral Citation Number: [2019] EWCA Civ 1924

Case No: B3/2019/1265

IN THE COURT OF APPEAL (CIVIL DIVISION)
ON APPEAL FROM THE HIGH COURT OF JUSTICE
QUEEN'S BENCH DIVISION
THE SEROXAT GROUP LITIGATION
The Honourable Mrs. Justice Lambert DBE
CLAIM NO. HQ07X04076

Royal Courts of Justice
Strand, London, WC2A 2LL

Date: 08/11/2019

Before :

THE SENIOR PRESIDENT OF TRIBUNALS
LORD JUSTICE HAMBLEN
and
LORD JUSTICE PETER JACKSON

Between :

Bailey & Ors	**Claimants/ Appellants**
- and -	
GlaxoSmithKline	**Defendant/ Respondent**

Michael Kent QC, Niazi Fetto, Harry Lambert & Juliet Stevens (instructed by **Fortitude Law**) for the **Appellants**
Charles Gibson QC, Malcolm Sheehan QC, Adam Heppinstall, James Williams (instructed by **Addleshaw Goddard LLP**) for the **Respondent**

Hearing date : 31 October 2019

Approved Judgment

Lord Justice Hamblen :

Introduction

1. This appeal concerns an action for damages for personal injury brought by the appellant Claimants in which it is alleged that Seroxat, a prescription-only antidepressant and one of a class of Selective Serotonin Re-Uptake Inhibitors or SSRIs, is defective within the meaning of the Consumer Protection Act 1987 ("the CPA").

2. The Claimants appeal against the decision of the trial judge, Lambert J, as to the scope of the Claimants' case on defect. In summary, she held that that case was limited to the risks of Seroxat relative to comparator SSRIs in respect of symptoms on discontinuation (the "worst in class" case) and could not be extended to the relative risks and benefits of Seroxat and its comparators more generally ("the risks/benefits case"). In consequence she held that, in considering whether the safety of Seroxat is such that persons generally are entitled to expect, the Claimants were not entitled to advance the case that Seroxat has no particular benefits relative to other drugs in the appropriate comparator group.

3. As a result of this ruling the ten week trial was adjourned pending determination of any appeal. Her ruling is set out in a reserved judgment of 9 May 2019, [2019] EWHC 1167 (QB) ("the judgment").

The legal framework

4. The CPA is the United Kingdom's implementation of the Product Liability Directive 85/374/EEC ("the Directive").

5. The Directive created a no-fault liability regime for defective products. Producers of products are liable for injury to persons or damage to certain kinds of property if a claimant can establish that the loss was caused by "a defect in the product".

6. Section 3 of the CPA sets out when there is a "defect in the product". It provides as follows:

> "(1) Subject to the following provisions of this section, there is a defect in a product for the purposes of this Part if the safety of the product is not such as persons generally are entitled to expect; and for those purposes "safety", in relation to a product, shall include safety with respect to products comprised in that product and safety in the context of risks of damage to property, as well as in the context of risks of death or personal injury.
>
> (2) In determining for the purposes of subsection (1) above what persons generally are entitled to expect in relation to a product all the circumstances shall be taken into account, including—
>
> (a) the manner in which, and purposes for which, the product has been marketed, its get-up, the use of any mark in relation to the product and any instructions for, or warnings with respect to, doing or refraining from doing anything with or in relation to the product;

> (b) what might reasonably be expected to be done with or in relation to the product; and
>
> (c) the time when the product was supplied by its producer to another;
>
> and nothing in this section shall require a defect to be inferred from the fact alone that the safety of a product which is supplied after that time is greater than the safety of the product in question."

7. In determining whether a product fails to meet the entitled expectations of persons generally, section 3(2) accordingly provides that "all the circumstances shall be taken into account" and sets out a list of non-exhaustive factors which the Court is required to take into account.

8. Recent guidance as to the interpretation of section 3 is provided by the decision of Hickinbottom J in *Wilkes v DePuy International Limited* [2018] QB 627. In that case he held at [78] that "assessment of whether the safety of a product is at an acceptable level requires a holistic approach." On the question of whether risk/benefit is a relevant circumstance Hickinbottom J held that "any assessment of its safety will necessarily require the risks involved in use of that product to be balanced against its potential benefits including its potential utility" and that "risk-benefit may lie at the heart of the question of appropriate level of safety of a medicinal product for the purposes of the Act".

The pleaded case on defect

9. At paragraph 5 of the Particulars of Claim dated December 2007 ("the POC") the Claimants contended how the product was allegedly defective:

> "5.1 - The product was defective as defined in the Directive and the Act because the safety of the Product was not such as persons generally were entitled to expect **in that the capacity of the Product to cause adverse effects consequent upon or following discontinuance (withdrawal) was such as to prevent or make more difficult the ability of users to discontinue, withdraw from or remain free from taking the product, to an extent greater than other SSRIs** (emphasis added);
>
> 5.2 - (a) the adverse effects, and (b) the need to continue taking the product, amount to a personal injury."

10. At paragraph 12 of the Particulars the defect alleged was stated to be that:

> "12.1 - The **Product** had the capacity to cause **adverse effects on discontinuance (withdrawal)** which were injurious, and which were such as would prevent or make it more difficult to withdraw from, discontinue or remain free from taking the product;

12.2 - **The capacity of the Product to cause such adverse effects was greater than with other SSRIs**;

12.3 – Persons generally are and were at all relevant times concerned about whether antidepressants were "addictive" in the sense that, amongst other things, it could be difficult to discontinue taking the mediation... Accordingly, persons generally are and were entitled to expect that:

12.3.1 – the Product would not be marketed or sold, or further marketed or sold, until any such adverse effects on discontinuance that were identified as potentially present in pre-marketing trials or in post-marketing surveillance studies had been fully assessed as to their nature, incidence and extent;

12.3.2 – the Product would not have the potential to cause such adverse effects upon discontinuance in terms of incidence or severity as would make it difficult to discontinue taking the medication;

12.3.3 – the Product would be no more likely to cause such adverse effects upon discontinuance than other SSRI's which could be prescribed for the same condition;

12.3.4 – **insofar as there was therapeutic benefit available from the Product not available from any other SSRI (which in respect of the main indications for which the same was marketed is denied),** and in any event,

12.3.4.1 – the Product would carry a clear warning in relation to adverse effects upon discontinuance..."

(emphases added).

11. Before serving its Defence, the respondent Defendant requested clarification of the POC in a Request for Further Information dated 19 February 2008. The Claimants provided a Reply to the Request for Further Information on 23 May 2008. The answers given to Questions 6 and 7 are of particular relevance:

"Question 6: In contending that Seroxat was defective for the reasons alleged in paragraph 5.1 of the Particulars of Claim, **is it the Claimant's case that the benefits of Seroxat against other SSRIs for a particular Claimant are material or to be taken into account?"**

To this question 6, the Claimants answered: "**No.**"

"Question 7: If so: (a) is it contended that Seroxat had lesser benefits for every Claimant than other SSRIs?; (b) please identify each benefit and each SSRI being referred to?"

> To question 7 (a), the Claimants answered: "Strictly, given the answer to 6, an answer is not required. However, in the event that potential benefit is determined to be of relevance, the Claimants denies (sic) that the Product had or has any or any greater effectiveness or other substantial benefit when compared with other SSRIs."
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> To question 7 (b), the Claimants answered: "No answer required, given the answer to 6"
>
> (emphases added)

12. In relation to paragraph 12.3.4.1. there was the following Question and Answer:

> R: "Is it the Claimants' contention that even if there were therapeutic benefits available from Seroxat not available from any other SSRI, Seroxat should have carried the warnings identified at paragraphs 12.3.4.1 to 12.3.4.3?
>
> A: **This is irrelevant** but the answer is yes."
> (emphasis added)

13. Following this exchange, the Defence was then served on 15 September 2008. This challenged the lawfulness of the Claimants' approach to defect, pleading at paragraph 39 as follows:

> "39. For the avoidance of doubt, it is denied that a defect, within the meaning of the 1987 Act, in a prescription-only medicine can be established by comparing the incidence and/or severity of a particular adverse reaction associated with that medicine against the incidence and/or severity of that adverse reaction associated with another prescription-only medicine. The producer of a prescription-only medicine cannot properly compare its medicine with all other "comparator" medicines either at the stage of development, post marketing or in its product literature."

14. The Defendant's case as to the lawful approach to defect was set out at paragraph 40 as follows:

> "40. Without prejudice to the foregoing denial, it is averred that any proper comparison between medicines would have to include a comparison of the relative risk/benefit profiles of the medicines being compared, both generally and for the particular Claimant in question. Such an analysis would include consideration of:
>
> (a) The relative efficacies of the medicines being compared.
>
> (b) The time likely to be taken to achieve steady state and, therefore, to achieve therapeutic efficacy.

> (c) The indications and contra-indications of the medicines being compared.
>
> (d) The available formulations of the medicines being compared.
>
> (e) The risks associated with the medicines being compared, including those associated with a longer half-life, for example, in overdose and when switching from one medication to another; and
>
> (f) The adverse reactions associated with the medicines being compared."

15. In addition, the Defence challenged the Claimants' case on the facts, denying that, when compared with other drugs in the appropriate comparator class, Seroxat was associated with a capacity to cause adverse effects on discontinuance which were injurious and which were such as would prevent or make it more difficult to withdraw from, discontinue, or remain free from taking Seroxat to a greater degree than with other SSRIs.

16. In relation to the Claimants' alternative case that Seroxat was defective because its product literature did not contain warnings, it was pleaded as follows at paragraph 49(c):

> "(c) Yet further and in any event, as explained above there was no basis for distinguishing between Seroxat and other SSRIs in relation to efficacy or nature of adverse reactions..."

17. In their Reply the Claimants joined issue with the Defence generally but did not seek to amend their case to plead a positive "holistic" risks/benefits case if, as the Defendant contended, the "worst in class" case involved a wrong approach. Nor did it assert that any assumptions were to be made or inferences drawn in respect of a risks/benefits case.

18. Following the Defence, a Group Litigation Order was made by Senior Master Whittaker on 29 October 2008 ("the GLO"). The GLO listed 11 issues ("the GLO Issues"), the first two of which set out the relevant issues on defect as follows:

> "a) Does Seroxat have a "capacity to cause adverse effects consequent upon or following discontinuance (withdrawal) such as to prevent or make more difficult the ability of users to discontinue, withdraw from or remain free from taking" Seroxat to a greater extent than all other Selective Serotonin Re-Uptake Inhibitors?
>
> b) Should the alleged defect in Seroxat, a prescription-only medicine, be established by comparing the incidence and/or severity of adverse reactions associated with that medicine against the incidence and/or severity of adverse reactions associated with another prescription-only medicine?"

The procedural background

19. The protracted history of this litigation is set out in the judgment of Foskett J of 4 February 2016, [2016] EWHC 178 (QB) ("Foskett 1").

20. In summary, following the GLO made in October 2008 the litigation proceeded until shortly before a trial of the GLO Issues listed to take place before Mackay J in February 2011, when public funding was withdrawn on a merits basis. This led to the adjournment of the trial and the action was effectively stayed until it came back before Foskett J in 2015. During the intervening period of over four years a large number of the Claimants discontinued their claims, leaving only around 124 Claimants in the action. The remaining Claimants challenged unsuccessfully the decision to withdraw public funding but managed to obtain alternative funding and a new counsel team was instructed.

21. Foskett J case managed the case from October 2015 until February 2018. During this time he gave three reserved judgments. In addition to Foskett 1, there was a judgment of 29 July 2016, [2016] EWHC 1975 (QB) ("Foskett 2") and a judgment of 1 March 2017 [2017] EWHC 377 (QB) ("Foskett 3").

22. At [4] of the judgment the judge accurately summarised the rulings made by Foskett J, so far as presently relevant, as follows:

> "4. The first question confronting Foskett J was whether the claim should be allowed to proceed given the reason for the trial in 2011 having been vacated and the prolonged interval before it had been restored before the Court. In his judgments of February 2016 and March 2017 Foskett J determined that the fair course was to allow the litigation to go forward, but only on the basis that the Claimants' case should remain as pleaded at the date of the vacated trial. I will return to those judgments later but pause here to note that Foskett J set out his analysis of the pleadings and the parties' respective cases in some detail in those two judgments as it was the necessary context for his handling of the case management issues which arose. He recorded in March 2017 that the accuracy of his earlier summary (in February 2016) of the essential nature of the case advanced on behalf of the Claimants was common ground between the parties. Neither ruling was the subject of appeal."

23. The judge was appointed trial judge in autumn 2018. Two pre-trial reviews were conducted before her in November 2018 and February 2019. The latter pre-trial review concerned the scope of the trial, an issue determined by her in a reserved judgment of 14 February 2019, [2019] EWHC 337 (QB) ("Lambert 1"). As a result, an order was made as to the issues to be determined at trial.

24. The trial commenced on 29 April 2019 and was listed for 10-12 weeks.

25. The current issue as to the scope of the Claimants' case on defect arose during the Claimants' opening. The judge allowed the Claimants to complete their opening and on 2 May 2019, after hearing argument, she made the following decision:

> "The issue which arises is whether in considering whether the safety of the product, Seroxat, is such as persons generally are entitled to expect, the

> Claimant is entitled on the pleadings to advance the case that Seroxat has no particular benefits relative to other drugs in the appropriate comparator group. The Claimant is not entitled to do so.
>
> As recorded in judgment of February 2019, the relative risks and benefits of Seroxat and its comparators do not form one of the issues at trial, other than in respect of discontinuation symptoms; and they do not form one of the issues at trial because of the Claimant's pleaded case.
>
> It does not follow from the Defendant's pleadings and, in particular, from the absence of a positive pleaded case on the benefits of Seroxat compared with other drugs in the comparator group (save in respect of the number of conditions for which Seroxat is licenced) that the Defendant has conceded that Seroxat has no particular relative benefits and/or that the Claimant is entitled to advance the case that Seroxat has no particular relative benefits."

26. Reasons for that decision were given in the judgment, handed down on 9 May 2019.

The judgment

27. The judge gave the following principal reasons for her decision:

(1) The case advanced in the Claimants' opening was not consistent with the pleadings. "The effect of the case now advanced by the Claimants is that the Court is being invited to take into account, when considering the safety of the drug, the relative benefits of Seroxat compared with other comparator drugs; and to take them into account on the basis that the drug has no such relative benefits. This is not the pleaded case" [32(a)].

(2) In circumstances where the Claimants had pinned their colours to the mast of the "worst in class" case, the Defendant was entitled to assert that as a matter of law the Claimants' approach to defect was flawed and was under no obligation to advance a positive case as to any relative benefits which Seroxat might have, nor did it do so - "The fact that it did not do so is not a concession that no such benefits existed" [32(b)].

(3) The only limited concession which the Defendant made in the pleadings was that, so far as efficacy of the drug is relevant, there was no basis for distinguishing Seroxat from other SSRIs (paragraph 49(c) of the Defence). That amounted to no more than an admission by the Defendant that, so far as the drug acts as a treatment for its licensed indications (e.g. anxiety or depression), there was nothing to choose between it and other SSRIs [32(c)].

(4) The Claimants' submission that the Defendant, by its failure to set out a positive case in respect of the range of relative benefits associated with the drug, had conceded that no such benefits exist, was wrong. Given the Defendant's case that the necessary holistic assessment should include assessment of relative risks and benefits across the drugs class, "it would be surprising if in fact the Defendant had conceded that no such benefits exist" [32(d)].

(5) Foskett J's analysis of the nature of the Claimants' case was correct. He rejected the suggestion that the risks/benefits case was part of the Claimants' case and ruled in Foskett 3 that it would be too late for it to be so – "the way in which the claim is now being advanced by the Claimants flies in the face of that ruling. There was no appeal from Foskett J's ruling" [32(e)].

(6) The Claimants could have pleaded a risks/benefits case by amending their pleadings in response to the Defence but had not done so [32(f)].

(7) That there may be expert evidence to be deployed at trial to support the Claimants' case that there is a level playing field across all the drugs in the appropriate class was disputed and in any event was not relevant. "The fact however is that given that the relative benefits of the drug were not in scope the experts have not examined the topic. Further, it would be too late to do so now. One point of agreement (and the only point of agreement it seems) between Ms Perry and Mr Gibson is that neither are ready or able to embark upon an examination of the particular relative benefits of Seroxat in this trial" [32(g)].

(8) There was no application before the Court to amend the POC. Had one been made, it would have been refused – "It is now too late" [33].

(9) "It would cause unfairness to the Defendant if the case were permitted to go forward on the understanding/assumption/inference that when considering whether Seroxat is defective the drug has no relative benefits compared with other SSRIs (or others in the appropriate comparator class)" [33].

28. The judge's concluding observation was as follows:

> "35. ...the issue which is addressed in this ruling (and which has taken considerable court time to ventilate) has already been covered, centrally, by Foskett J in March 2017 and also by myself in my ruling in February 2019. As I have already said, there has been no appeal from either of those rulings. What the Claimants have sought to do by opening the case in the way they have, is to seek to justify the limited approach (said to be flawed by the Defendant) on defect on the basis of an asserted concession by the Defendant that if a wider risk/benefits analysis were to be undertaken it would reveal a level playing field across the class of drugs. This case simply does not square with the Claimants' pleaded claim nor with Foskett J's analysis, nor mine. If either Foskett J or I were thought to be wrong in our analysis, then the proper course would have been to have appealed the relevant rulings. It is now too late to do so."

The grounds of appeal

29. The grounds of appeal are as follows:

(1) The judge erred in preventing the Claimants advancing the case that Seroxat had no particular benefits relative to other drugs in the appropriate comparator group when:

a. it was not for the Claimants to identify particular relative benefits associated with Seroxat and other SSRIs;

b. the Claimants had in the POC at paragraph 12.3.4 asserted that there was no relevant therapeutic benefit available from the product not available from any other SSRI;
c. the Defendant in its Defence had not controverted that assertion save that it relied upon only one alleged relative benefit attaching to Seroxat namely that it was licensed in the UK for more indications than other SSRIs; indeed
d. the Defendant had expressly conceded that "there was no basis for distinguishing between Seroxat and other SSRIs in relation to efficacy or nature of adverse reactions"; and
e. it was therefore common ground on the pleadings that, save in respect of the greater number of indications for which Seroxat is licensed, there was no relative benefit attaching to Seroxat.

(2) The judge erred in identifying a qualification or cutting down of the Claimants' case in answers to a request for further information of the POC when such answers could not be read as so doing and in any event repeated the assertion that there were no relevant relative benefits to Seroxat compared with other SSRIs.

(3) The judge wrongly treated observations of Foskett J, in the course of a ruling on an application to exclude parts of an expert evidence report as containing inadmissible material, as amounting to a finding or holding that the Claimants' case did not rely on absence of relative benefit or that it had become cut down or qualified so as to exclude such a case by answers to a request for further information or by statements made by counsel.

30. Mr Gibson QC for the Defendant submits that the Court should consider Ground (3) first. If the judge was correct that her judgment was merely confirmatory of prior, unappealed rulings made by Foskett J and the judge herself as to the scope of the Claimants' case, then the appeal must fail regardless of how the pleadings are to be analysed (Grounds (1) and (2)). We agree with that approach.

Ground (3)

31. The prior rulings of particular relevance are those set out in Foskett 3 and Lambert 1 ("the Prior Rulings").

32. Foskett 1 had concerned whether the Claimants should be allowed to continue with the proceedings given the long hiatus which had occurred. In his judgment Foskett J identified the "essential" nature of the case on defect advanced as being as follows at [5]:

> "....what is sought to be alleged in these proceedings is that it is worse than other drugs of a similar nature in relation to symptoms following discontinuation of its use. It is pleaded on behalf of the Claimants that "the capacity of [Seroxat] to cause adverse effects consequent upon or following discontinuance (withdrawal) [is] such as to prevent or make more difficult the ability of users to discontinue, withdraw from or remain free from taking [it], to an extent greater than with other SSRIs."

33. Foskett J noted at [8] that this essential factual allegation was denied and that in any event "the issue of whether a prescription-only drug is "defective" cannot be determined simply by "comparing the incidence and/or severity of a particular adverse reaction against the incidence and/or severity of the same adverse reaction after treatment with another [drug]"".

34. Foskett J also set out at [19] the issues for determination as ordered by Master Whitaker, namely the GLO Issues.

35. In Foskett 1 the judge concluded as follows at [130]:

> "... I wish to proceed on a step-by-step basis with a careful eye on the costs of each step. I do not intend to "micro-manage" this litigation, but I need to see to what extent certain crucial stages are capable of being achieved and at what cost before I can obtain a sense of how realistic it is that it can proceed."

36. In Foskett 2, continuing his step-by-step approach, Foskett J permitted substitution of the experts by the Claimants and allowed updated reports to be provided. In so ruling, Foskett J observed at [47] that the "high point" of the Claimants' case was that set out in [19] of Foskett 1 – i.e. the GLO Issues.

37. Foskett 3 followed a two day hearing on 21 and 22 February 2017. One of the issues for determination was whether there were parts of the report of Professor Healy, one of the Claimants' experts, which should be redacted. This involved a close analysis of the Claimants' pleaded case. The judge at [20] of the judgment accurately summarised the most relevant observations made by Foskett J in addressing the scope of the Claimants' case, as follows:

> "a. at [11] it was common ground that he had summarised the essential nature of the case advanced on behalf of the Claimants accurately in his first judgment;
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> b. at [12] that the Claimants' primary and secondary case were translated into the agreed issues set out in the GLO;
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> c. at [13] that Mr Gibson QC (for the Defendant) had characterised the primary allegation as being that Seroxat was "*worst in class*", in other words that Seroxat was the worst in the class of SSRIs because of the greater difficulty relative to other SSRIs of a user of Seroxat discontinuing his/her use of the drug and the consequent prolongation of discontinuation symptoms. Foskett J approved this characterisation of the Claimants' case, stating that it was accurate;
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> d. at [15] the Defendant's case throughout the litigation had been that the approach to the primary issue adopted on behalf of the Claimants was fundamentally misconceived and that the Defendant's case was that it was necessary to look at a prescription only drug of this type "in the round" before deciding that it is defective, taking into consideration amongst other

things, a risk/benefit analysis of its features. This case had been advanced in the Defence served in September 2008 at paragraph 40 and then put in issue in the Amended Reply. Foskett J then set out the Request for Further Information served by the Defendant concerning the need to address the relative benefits of Seroxat (against other SSRIs) in considering whether the drug was defective and the Claimants' negative response to this Request;

e. at [20] the Defendant's assertion that, since the close of pleadings, the Claimants' case had proceeded only on the basis of the "worst in class for discontinuation symptoms for SSRIs" allegation and the associated allegation of failure to warn that Seroxat was "worst in class" in this respect was justified;

f. at [23] since the action had been before him, it had been the consistent position of the Claimants' team led by Ms Perry QC that the case would continue (if permitted to do so) only on the basis of the pleaded case and the issues defined in the way in which he had described them. There had been no application to amend the Particulars of Claim nor to expand upon the issues identified in the GLO;

g. at [23] his case management of the claim had been intended "*purely to enable the effective resurrection of the issues that came to rest in 2011*" (Foskett J's emphasis);

h. at [24] any attempt on behalf of the Claimants (or the Defendants) to expand the case "*outside those well-defined parameters*" would not have his approval. This is the "*unequivocal starting point*" for the issue in hand (which was the scope of the report by Professor Healy);

i. at [27] the issues for his determination of the litigation have been clearly and closely defined over a period of years and subject to the updating of the disclosure exercise and the expert evidence, the parameters for the forthcoming trial have not changed. The new legal team has not sought to change things although there has been "*a hint in some of Mr Lambert's submissions that there is now a desire to engage, at least to some extent, in a risk/benefit analysis, something which had previously been expressly disavowed. If there is any such a desire or intention, then the short answer to it is that it is now too late to do so.*""

38. Foskett J, the judge with the responsibility for managing the case, thereby made it clear that the Claimants' pleaded case on defect was limited to the "worst in class" case, as reflected in the GLO Issues. On that basis he ordered that certain redactions be made to Professor Healy's report. He also made it clear that the case would go forward on the basis of these "clearly and closely defined" issues and that it was now too late for the Claimants to seek to expand their case to cover an analysis of risks/benefits.

39. The Claimants did not appeal Foskett J's ruling about the scope of their case on defect nor his Order which reflected it. Nor did they write to the Court or to the Defendant following the hearing setting out any disagreement with Foskett J's characterisation of the issues in the case or asserting any alleged inability on their part to appeal Foskett J's determinations.

40. It is submitted on behalf of the Claimants that the rulings were given at a Case Management Conference ("CMC") at which Foskett J was not asked to and did not purport to rule on the question whether the Claimants were entitled to present a risks/benefits case, that the orders made following those CMCs contained no such decision and that there was therefore no order made which needed to, or could, be appealed. I disagree.

41. The judge had made clear his interpretation of the Claimants' pleaded case and, on that basis, had made determinations as to the legitimate ambit of expert evidence, had identified the issues for trial, and had set out how the case was to be case managed going forward. He had also stated in terms that he would not approve any expansion of the case outside the parameters he had defined. Unless and until his decision as to scope was challenged the case was going to be conducted and managed in the light of that determination and the parties would be expected so to prepare for trial. If the Claimants were to challenge that approach this was the time to do so. The Claimants could have sought to appeal against the judge's decision as to scope but did not do so. There was no necessity for that ruling to be expressly reflected in the terms of the order made in order to be able to appeal. It was a decision fundamental to the case management of the case and was manifestly capable of being appealed, albeit that the prospects of a successful appeal against such a decision would have been slight.

42. As the judge observed at [22], "notwithstanding Foskett J's case management and his very clear statement of the issues to be addressed at trial", it transpired that there remained a tension between the parties concerning the nature and extent of the Claimants' case. That led the judge to order the parties to produce a list of questions or issues which they considered should be decided at trial. These matters were addressed at the pre-trial review in February 2019 and were determined in Lambert 1.

43. In Lambert 1 the judge stated that the issue for her determination was "the scope of the trial" and in particular "the scope of the Claimants' case on defect". In relation to the Claimants' entitlement to raise the risks/benefits case, in his written submissions Mr Kent QC for the Claimants made essentially the same submissions as were later to be made at the opening of the trial. In reaching her decision the judge stated as follows:

    (1) "I accept, that there must be absolute clarity in the Claimants' case on defect. It is that defect which must cause the injury. It is in respect of that defect that the Defendant is entitled to raise its development risk defence. The Claimants' case on defect drives the scope of the expert evidence and the focus of the trial" [11].

    (2) "There is no application before me in connection with the drug's risk/benefit profile. Although Mr Kent's note on scope suggested that he may be asking me to rule that the drug's risk/benefit profile should be included as an issue at trial, Mr Kent did not in the event make that application. The Claimant's list of questions for trial did not include that topic. Both parties agreed that the topic was not one to be covered at trial" [10].

(3) "Mr Gibson agrees that the particular advantages and disadvantages of the drug are not in scope; he has pleaded no positive case and is not running a positive case on risk/benefits. The Claimant's pleaded case, as clarified in the Response to the Request for Further Information, was that, irrespective of any particular benefits of Seroxat, the drug was nonetheless defective" [11].

(4) In relation to risks/benefits "there is no application before me concerning this issue. There is no need for me to make a ruling upon whether it is in or out of scope: both parties, from their respective lists of questions, agree that it is not in scope. I note that no positive case on the benefits of Seroxat is advanced by the Defendant either in its pleaded case nor, I am told, in the expert evidence. **Whether there are, or not, particular benefits associated with Seroxat will therefore not feature at trial** and, as Foskett J ruled in March 2017, it is now far too late to expand the scope of the trial to include evidence of risks/benefits" [15] (emphasis added).

(5) "I order therefore that the lists of issues produced by the Defendant will stand as the list of issues to be determined at trial. In so doing, I am not shutting the Claimant out from examining the nature, incidence and duration of adverse events on discontinuation which is a necessary element of the exercise of determining the Claimant's comparative case" [17].

44. The judge therefore ruled in terms that the risks/benefits case would "not feature at trial" and that it was now "far too late" for it to do so, even if an application to that effect had been made, which it was not. She then made an order that the Defendant's list of issues "will stand as the list of issues to be determined at trial". That list of issues made it clear, as had the judgment, that any risks/benefits analysis was limited to the "worst in class" case. The first issue to be determined was expressed as follows:

> "(1) Is it appropriate in principle to assess whether the prescription-only medicine Seroxat is defective pursuant to s. 3 of the Consumer Protection Act 1987 ("the Act") by seeking to establish whether it is "worst in class" in that:
>
> (1)(a) It causes adverse effects on discontinuation which are (i) of a greater incidence; (ii) a greater severity; and (iii) a longer duration than the other medicines in the class; and that
> (1)(b) Such adverse effects prevent or make more difficult the ability of users to discontinue, withdraw from or remain free from Seroxat than is the case with the other medicines in the case?"

45. In the judgment the judge accurately summarised the relevant part of her decision in Lambert 1 as follows:

> "24. I also cleared the decks of a pleading issue which had arisen during the course of Mr Kent's submissions. It concerned the extent to which the relative risks and benefits of Seroxat (as compared with other drugs in the appropriate comparator class) were in issue at the trial and, if not, why not. At [15] of the judgment I ruled that the relative benefits of Seroxat would not form an issue at trial, noting that neither party submitted that the topic was in scope..."

46. If the Claimants wished to challenge the judge's ruling and her order as to the issues to be determined at trial this was the time to do so. On this occasion the judge's decision as to scope was expressly reflected in the order made. No attempt was made to appeal against the decision or order. No doubt this was done advisedly. The prospects of succeeding on appeal in introducing a risks/benefits case, in circumstances where no such application had been made before the judge, and she had made it clear that it would be far too late to seek to do so, were obviously very remote.

47. At the hearing of the appeal it was submitted by Mr Kent QC that there was no need to raise the risks/benefits case as an issue because, in the light of the pleadings, it was effectively a non-issue. This involves ignoring the considered way in which the case had been case managed and the issues had been carefully defined and delineated. It also ignores the fact that it would necessarily mean the issue of particular benefits featuring at the trial, in circumstances where the judge had expressly determined that it would not.

48. Against the background of the unappealed Prior Rulings, in my judgment it was plainly impermissible for the Claimants to seek to raise the risks/benefits case in opening their case at trial. Although this was done under the guise of an assumed "level playing field" with regard to the benefits and (by implication) the risks associated with Seroxat and its comparator drugs, this involved seeking to introduce the risks/benefits case as an issue at trial and would have necessitated evidence relating to it. It is obvious that any issue of relative risks/benefits would raise a wide ranging factual and expert inquiry, which all parties accepted had not been carried out.

49. The suggestion that the pleadings somehow allow such a case to be raised is beside the point. The Court had made clear its interpretation of the pleaded case in Foskett 3 (at the latest) and the case had been case managed on that basis up to the start of trial, as confirmed in Lambert 1. Neither of these decisions had been appealed. In any event, it would have been far too late to seek at trial to go back on the clear case parameters which the Court had set. To do so would also have involved obvious unfairness to the Defendant, as the judge found.

50. Active case management in accordance with the overriding objective will often involve the identification of a list of issues. That list of issues will generally be used to form the basis of the management of the case, of the need for disclosure and of the preparation of factual and expert evidence for trial, as it did in this case. Allowing parties at trial to expand the issues and the evidence needed in reliance on pleading points is to undermine such good case management. Certainly, there was no possible basis for doing so in this case given the decisions and rulings made and, in particular, the Prior Rulings.

51. In my judgment the judge was correct to decide that her judgment was merely confirmatory of the unappealed Prior Rulings. I entirely agree with the observations she made at [35] of the judgment, as set out above, and her conclusion that:

> "If either Foskett J or I were thought to be wrong in our analysis, then the proper course would have been to have appealed the relevant rulings. It is now too late to do so."

52. In these circumstances the appeal must fail regardless of how the pleadings are to be analysed (Grounds (1) and (2)).

Grounds (1) and (2)

53. Given the decision reached on Ground (3), it is not necessary to address these Grounds. I am, however, in complete agreement with the analysis of the pleadings carried out by both Foskett J and the judge. In particular: no positive case as to risks/benefits was raised by either party on the pleadings; there was no need for the Defendant to do so in order to meet the Claimants' case, and no conceded or agreed case on benefits can be inferred from the Defendant's failure to raise such a positive case. The pleaded case was always limited to the "worst in class" case.

Conclusion

54. For the reasons outlined above I would dismiss the appeal.

Lord Justice Peter Jackson:

55. I agree.

Sir Ernest Ryder, Senior President of Tribunals:

56. I also agree.