Neutral Citation Number: [2019] EWHC 1167 (QB)

Case No: HQ07X04076

IN THE HIGH COURT OF JUSTICE
QUEEN'S BENCH DIVISION

Royal Courts of Justice
Strand, London, WC2A 2LL

Date: 09/05/2019

Before :

MRS JUSTICE LAMBERT

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Between :

SANDRA BAILEY & OTHERS	**Claimants**
- and -	
GLAXOSMITHKLINE UK LIMITED	**Defendant**

- -
- -

Jacqueline Perry QC, Michael Kent QC, Niazi Fetto, Harry Lambert and Juliet Stevens (instructed by **Fortitude Law**) for the **Claimants**
Charles Gibson QC, Malcolm Sheehan QC, Andrew Kinnier QC, Adam Heppinstall and James Williams (instructed by **Addleshaw Goddard**) for the **Defendant**

Hearing dates: 29 April – 1 May 2019

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Approved Judgment

I direct that pursuant to CPR PD 39A para 6.1 no official shorthand note shall be taken of this Judgment and that copies of this version as handed down may be treated as authentic.

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MRS JUSTICE LAMBERT

MRS JUSTICE LAMBERT:

Introduction

1. This is an action for damages, brought by a large number of Claimants, arising from their use of the drug, Seroxat (a prescription only antidepressant and one of a class of Selective Seratonin Re-Uptake Inhibitors, or SSRIs) which is alleged to be defective under section 3 Consumer Protection Act 1987 ("the Act"). The trial started on 29 April 2019 and is listed for 10 to 12 weeks. An issue arose during the course of the Claimants' Opening which required an urgent ruling. I therefore heard submissions on the point and circulated my decision on 2 May 2019 with reasons to follow. This judgment sets out my reasons.

2. The Claimants were represented by Ms Jacqueline Perry QC and Mr Michael Kent QC with Mr Niazi Fetto, Mr Harry Lambert and Ms Juliet Stevens, the Defendant by Mr Charles Gibson QC, Mr Malcolm Sheehan QC, Mr Andrew Kinnier QC with Mr Adam Heppinstall, and Mr James Williams.

Procedural Background

3. The litigation has a particularly long history, the Particulars of Claim having been drafted as long ago as 2007. The procedural history of the litigation has been set out in detail in the judgment of Foskett J of February 2016 and I do not repeat it here. I note at this stage only that, following the service of the Defence, a Group Litigation Order was made by Senior Master Whittaker in October 2008 listing 11 common or related issues of fact or law for determination at trial and that the litigation was proceeding along the usual lines until very shortly before the trial (which had been listed to take place before Mackay J in February 2011) when public funding was withdrawn on a merits basis. The effect of the withdrawal of public funding was that the trial was adjourned, and the action effectively stayed until it came back before the Court, this time before Foskett J, in 2015. During the hiatus 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. A new counsel team was instructed, led by Ms Jacqueline Perry QC.

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.

5. I was appointed trial judge in the Autumn of 2018. Two pre-trial reviews were conducted before me: in November 2018 and February 2019. Again, I will return to those hearings and the decisions which followed in due course.

The Pleadings:

6. The action is brought under the 1987 Act where, under section 3(1) a product is defective if the safety of the product is not such as persons generally are entitled to expect. Under section 3(2), in determining what persons generally are entitled to expect, all of the circumstances shall be taken into account.

7. The issue which has arisen during the course of the Claimants' Opening concerns the scope of the Claimants' case on the pleadings; specifically whether, in determining whether the safety of the drug is such as persons generally are entitled to expect under section 3 of the Act, the Court should infer or assume that Seroxat has no relative benefits (when compared with other drugs in the appropriate comparator class). The Claimants submit that the Court should assume "a level playing field" (as it was put) of risks and benefits as between the drugs in the appropriate comparator class save for the single product characteristic of Seroxat which is said to constitute the "defect." They submit that this inference or assumption arises from the parties' respective cases on the pleadings. This is disputed by the Defendant.

8. I set out below the key sections of the pleadings.

9. The Particulars of Claim (dated December 2007) identify the Claimants' generic case on defect in paragraphs 5 and 12:

> "*5. The Claimants contend that:*
>
> *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;*
> *5.2 (a) the adverse effects, and (b) the need to continue taking the Product, amount to a personal injury."*

At paragraph 12 the defect alleged is 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 medication… 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 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 SSRIs 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*
> *12.3.4.1 in any event, the Product would carry a clear warning in relation to adverse effects upon discontinuance…*

10. Before serving its Defence, the Defendant requested clarification of a number of sections of the Particulars of Claim. The Request included the following:

> *"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?"*
> *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?"*

Question 6 was answered: *"No."*

Question 7 (a) was 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"*

11. The Defence was served in September 2008. The Defence challenged the lawfulness of the Claimants' approach to defect under section 3 of the Act. At paragraph 39 it was pleaded that:

> *"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."*

12. The Defence then set out what the Defendant asserted to be the lawful approach to defect in paragraph 40:

> *"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."*

13. In addition to this head-on challenge to the Claimants' approach to defect, the Defence also addressed 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.

14. Following the service of the Defence, a Group Litigation Order was made by Senior Master Whittaker. The list of issues includes the Claimants' case on warnings, the Defendant's development risk defence, generic causation and limitation. For present purposes only the first two of the 11 issues on the list are relevant. They are:

> *"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?"*

15. Following the GLO, there were further pleadings: a Reply and an Amended Reply and a number of requests for further information and notices to admit. For present purposes the only further point that I need record is that the Defendant confirmed that, so far as efficacy of the drug was concerned, there was no current basis for distinguishing between Seroxat and other SSRIs when licensed for the same clinical indication.

16. This was the background against which the action came before Foskett J for his determination on whether the case in 2015 should be permitted to proceed at all, and if so, on what basis.

Foskett J's Rulings:

a) [2016] EWHC 178 (QB)

17. The action came before Foskett J for case management in October and December 2015. The judgment was handed down on 4 February 2016. The judgment records at [6] the "*essential (and primary) nature of the case advanced*" to be "*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.*" And "*If that allegation is established as a matter of fact, it is alleged that it gives rise to the conclusion that the drug is "defective" within section 3 of the Consumer Protection Act 1987*". He also noted the alternative and secondary allegation that Seroxat was defective because it is marketed and sold without warnings that it causes more or greater symptoms on discontinuation than all other SSRIs.

18. At [8] he noted that "*all these allegations are hotly contested by the Defendant, the manufacturer of the drug. Drawing from the initial Skeleton Argument of Mr Sheehan and Mr Andrew Kinnier for the Defendant in order to determine the response to the claim, the essential factual allegation to which I have referred is denied and it is said, in any event, that 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]"*." He set out the list of generic issues derived from the GLO at paragraph 19 observing that they constituted the "*essential issues in the case*."

19. Foskett J did not reach a settled view concerning the long-term future of the litigation, preferring to case manage in stages whilst keeping a weather eye on the funding situation, the costs of the litigation and overall value of the claim. As he remarked, he did not wish to micro-manage the litigation but wanted to be satisfied that certain crucial stages could be achieved and the associated costs involved with each stage. He gave directions for amongst other things, the selection of lead claims, expert evidence and Schedules of Loss. However, as he observed in the further hearing later that year [2016] EWHC 1975 (QB), paragraph 45, "*I made it clear during the hearing that I was*

approaching the current issues on the basis of the pleaded case…For my part, the currently pleaded issues are the issues at stake in the litigation and there is no scope for expansion." At paragraph 47 He also noted that the "*high point of the Claimants' case*" was as set out in the GLO list of issues.

b) [2017] EWHC 377 (QB)

20. A further case management hearing took place in February 2017 with a judgment following in March 2017. At the hearing, the Claimants were represented by Mr Lambert. In his ruling, Foskett J made the following observations:

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;

b. at [12] that the Claimants' primary and secondary case were translated into the agreed issues set out in the GLO;

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;

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.*"

21. There was no appeal from this ruling. There then followed a series of further case management and costs hearings resulting in a substantial security for costs being given by the Claimants' litigation funders. I took over as trial judge in November 2018.

The February Pre-Trial Review: [2019] EWHC 337(QB)

22. As I set out in my judgment of February 2019, it was clear from Mr Kent's submissions at the hearing in November 2018 (the first before me) that, notwithstanding Foskett J's case management and his very clear statement of the issues to be addressed at trial, there may yet be a tension between the parties concerning the nature and extent of the Claimants' case. In the hope of avoiding time being wasted at trial determining outstanding issues, I ordered the parties to produce a list of questions or issues which they considered should be decided by me at trial for submissions at the pre-trial review in February 2019. This process did indeed flush out a significant difference although, as it turns out, it did not serve to iron out all of the issues, as I had intended it would.

23. The issue which I determined in February 2019 was whether the Claimants' case was exclusively comparative (the "worst in class" allegation) or whether, as submitted by Mr Kent, the pleadings included an allegation of a primary ("freestanding") defect based on the incidence, duration and severity of the symptoms on discontinuance of the drug. I ruled that the Claimants' case did not include the freestanding defect allegation (see [12] and [13] of judgment).

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. At [16] I recorded that, by the Claimants' response to the Request for Further Information the Claimants had made the point that their case on defect was independent of and irrespective of any benefits, relative or otherwise that the drug might have. Given this response, the Defendant had been entitled to limit their case to a locking of horns with the Claimants' in their approach to defect as a matter of legal principle and to a denial of the claim on the facts. The Defendant had not sought

to plead a positive case on risks and benefits as a further or alternative limb of its defence. Given the Claimants' pleading, there was no need for it to do so.

25. I annexed to the Order the list of issues to be determined at trial. Although the order had been re-jigged, the issues largely reflected those set out in the GLO.

The Issue for my determination:

26. The Claimants' written opening was served on 5 April 2019. It contained the following at paragraphs 57, 58 and 59: "*it is not and has never been the Claimants' case that a product can be shown to be defective within the CPA 1987 merely by identifying one negative and/or undesirable aspect of it whilst ignoring any advantages. It is a reductio ad absurdum on the part of the Defendant that fails to recognise the case being advanced by the Claimants*." The submission went on "*what is being advanced herein is indeed a holistic approach, namely that whatever benefits asserted by the Defendant for this product in these proceedings, they are outweighed by the risks and problems associated with DS, having regard to inter alia the existence of equally efficacious products which do not have those risks/problems. In simple terms, if all the SSRIs are equally efficacious (as is agreed), why would any patient take the one which is "worst in class" for DS*?"

27. Correspondence from the Defendant followed on, predictably quickly, from service of the Claimants' opening. The Court was reminded by the Defendant that there had been a slew of rulings from the Court in which the Claimants' case had been defined; that the case was about whether Seroxat was "worst in class" for discontinuation symptoms and that, in both the ruling of Foskett J of March 2017 and my ruling of February 2019, the relative benefits of Seroxat whether in comparison with other SSRIs or otherwise had been determined to not form part of either parties' case. The Defendant stated that it was not open to the Claimants to shift the goal posts and now maintain that their case on defect was "holistic" and that the relative benefits or risks of Seroxat (other than in respect of symptoms on discontinuation) should be taken into account by the Court when considering the circumstances relevant to safety: this was not their pleaded case on defect which focussed only upon the worst in class aspect.

28. The forensic effect of the point being made by the Claimants in their written opening emerged clearly only during the course of Ms Perry's oral opening submissions. Her submission was that, when the Court was considering whether Seroxat was unsafe (by reference to what persons generally are entitled to expect) the Court must "*start with a level playing field.*" In other words, the Court should assume that Seroxat has no particular benefits over and above other comparator drugs. Ms Perry submitted that "*if you start with products that all, basically, do the same thing, and no one of those products is said to be particularly better than the others. You, therefore, are starting at a position where – and the medical lecture support this – the only thing that somebody prescribing this drug should or needs to be concerned about is what are the downsides? What are the discontinuation effects? What are the discontinuation symptoms? Because if, ultimately, you've got five drugs all doing the same thing, it must follow that if they're all going to achieve the same result, but one of them is going to cause far more problems than the others, it isn't just a case of being worst in class*". Therefore, I should approach the question of whether the drug is not safe in all of the circumstances because there are "*no benefits*" associated with the drug but "*just burdens.*"

29. Ms Perry submits that her case is consistent with the pleadings. She argues that too much emphasis has been placed upon the response to the Request for Further Information (question 6) which, to adopt the language of Foskett J, appeared to disavow consideration of the relative benefits of the drug when considering whether it was an unsafe and therefore defective product. That response she submits should be viewed in conjunction with the response to question 7 which contained a denial that the product had any greater efficacy or other substantial benefit than other drugs in the class. Furthermore, she submits, the Defendant has admitted that Seroxat has no particular advantage so far as its efficacy is concerned. Ms Perry also submitted that it was up to the Defendant to plead the asserted relative benefits of the drug. It has not done so. In the absence of a pleaded case, the Defendant must be taken to have, in effect, conceded that Seroxat has no relative benefits. It has raised the issue of the lawfulness of the Claimants' approach to defect and yet not made an application for summary judgment or to strike out the Claimants' case. It should have done so. She submits that as the evidence has emerged, the experts support the case that in fact Seroxat has no particular benefits or indications over and above other drugs of a similar nature. As such, the Court should proceed on the basis of the facts as they have emerged irrespective of the state of the pleadings. Finally, she submits that, to the extent that Foskett J analysed the Claimants' case, he did not drill down into the detail of the pleadings; at the hearing before him which led to the March 2017 ruling she had been unable to attend and the Claimants had been represented by Mr Lambert who had limited knowledge of the case having only been instructed for a short period of time.

30. The Defendant submits that this approach represents a very significant and fundamental expansion on the Claimants' pleaded case. The Claimants' pleaded case on defect expressly and unambiguously excludes consideration of any possible relative benefits associated with Seroxat compared with other drugs in the comparator class and the case on defect focusses only upon one product characteristic, namely the alleged greater incidence, severity and duration of discontinuation symptoms. This is the case which the Defendant equally unambiguously challenged in its defence as a matter of law and on the facts. Foskett J correctly analysed the Claimants' case and the defence. In March 2017 Foskett J noted Mr Lambert's submissions on relative risks and benefits and in his ruling tackled the question of whether, on the pleadings, relative risks and benefits formed part of the circumstances relevant to the Claimants' case on safety and defect. Foskett J made it plain that they did not do so and that Mr Lambert's attempt to expand the case was impermissible and inconsistent with the basis upon which he was prepared to allow the claim to continue. I made a similar point in February 2019. Neither the Foskett rulings nor my ruling were appealed. If I or Foskett J had misinterpreted the pleadings, then the Claimants should have appealed. The Defendant has not, by deciding not to advance a positive case on benefits, conceded that no benefits exist. The Defendant has in its pleading simply responded to the claim as pleaded. The Defendant submits that the Claimants' case as set out in the opening represents a significant expansion of the case which, if permitted to be ventilated at trial, would result in unfairness to the Defendant: the disclosure exercise and the assembling of the expert evidence have all proceeded on the basis that the Claimants case is limited to the "worst in class" for discontinuation symptoms allegation. The experts have not been instructed to consider the relative benefits of Seroxat, precisely because this topic is not in issue in the case.

My Decision and Reasons

31. I have already informed the parties of my decision which is that, when considering whether the safety of the drug, Seroxat, is such as persons generally are entitled to expect, the Claimants are not entitled on their pleadings to submit that the drug has no relative benefits and that so far as relative risk and benefits are concerned, there is a "level playing field."

32. I made this decision for the following reasons:

    a. The case now advanced in the Claimants' opening is not consistent with the pleadings. The defect alleged in the Particulars of Claim is limited to the greater capacity of the drug to cause discontinuation symptoms (in respect of incidence, frequency and severity) compared with other similar drugs. Whilst appreciating that Ms Perry does not approve of the label "worst in class" as a shorthand for her case, I, like Foskett J, find it to be an accurate characterisation of the pleaded case. The case on defect does not include an holistic assessment of relative risks and benefits across the drugs in the group: the response which was given to question 6 in the Request for Further Information confirmed that benefits of the drug against other SSRIs for a particular claimant were not material or to be taken into account. As I noted in my ruling of February 2019, the Claimants were here stating that their case on defect was independent of and irrespective of any relative benefits which the drug might have. The fact that in a subsequent response, the Claimants asserted that (to the extent that it was relevant) the drug did not have any potential relative benefits, does not undermine the Claimants' case that relative benefits were not material to the consideration of defect. 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.

    b. The Claimants having unequivocally pinned their colours to the mast, the Defendant was entitled to lock horns with the claim as pleaded against it and assert that, as a matter of law, the Claimants' approach to defect was flawed. Again, as I noted in February 2019, the Defendant was under no obligation to advance a positive case as to any relative benefits which the drug might possess. The Defendant could have "further and alternatively" set out its stall as to any benefits or indications for use which Seroxat had in comparison with, say, citalopram or other drugs of a similar pharmacological make up. But it chose not to do so. The fact that it did not do so is not a concession that no such benefits existed. It might be said that the Defendant was, by taking the strategic approach that it did and not pleading the range of indications for Seroxat in comparison with other SSRIs, taking something of a risk; I am not determining the merits of the Defendant's legal challenge in this ruling which may or may not have merit. But it was an approach that the Defendant was entitled to take on the pleadings.

    c. The only limited concession which the Defendant has made in the pleadings is that, so far as efficacy of the drug is relevant there is no basis for distinguishing Seroxat from other SSRIs (see paragraph 49(c) of the Particulars of Claim and the Response to the Request for Further Information on that paragraph). At times, during Ms Perry's submissions, it appeared that she was reading this

statement as a concession that Seroxat had no relative benefits, rather than the statement being limited to a reference to therapeutic efficacy. I do not read the statement as amounting to anything 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 is nothing to choose between it and other SSRIs. Nor do I find that on any plain reading of the statement in paragraph 49(c) "efficacy" could sensibly be said to be referring to anything other than therapeutic efficacy.

d. Just pausing here and standing back from the Claimants' submission that the Defendant has, by its failure to set out its stall in respect of the range of relative benefits associated with the drug, conceded that no such benefits exist, it is clear to me that the submission is wrong. One prong of the twin attack (that is, the legal challenge) by the Defendant in its Defence is that the Claimants have failed to approach defect lawfully by failing to adopt an holistic assessment of relevant circumstances which impact upon the safety of the product and that such an assessment would or should include assessment of relative risks and benefits across the drugs class. Against this background it would be surprising if in fact the Defendant had conceded that no such benefits exist. I find that the Defendant has not done so.

e. Foskett J analysed the pleadings with care. He had to do so because the only basis upon which he was prepared to permit the action to continue was that the action was confined to the pleaded claim as at 2010/2011. I have set out the relevant excerpts from his judgments above and I do not accept that he, for whatever reason, failed to drill down into the issues in the case. Nor could he have been clearer in his analysis. His analysis identified correctly the nature of the Claimants' case. His understanding, as he recorded it, was that his analysis was common ground between the parties. In March 2017, he was faced with submissions by Mr Lambert that "*negative risk benefit*" was a relevant factor in assessing whether discontinuation problems were a defect (as part of all the relevant circumstances) and he rejected the submission that this was part of the Claimants' case ("*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… it is now too late to do so"*). It seems to me that 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.

f. The Claimants could have, in response to the Defence, sought to amend their pleadings and plead, even as an alternative case, that an holistic assessment including consideration of relative benefits and risks formed part of the circumstances which impacted upon safety and so defect. This did not happen. Mr Kent has submitted that it would have been impossible for the Claimants to have done this. He submits that the Claimants could not have, proleptically, set out to deny each and every possible relative benefit which might be asserted by the Defendant. I do not understand this point. On the basis of such expert evidence as was available to them, the Claimants could have pleaded as part of an holistic case on defect that there were no benefits or indications for prescribing Seroxat to any patient given its "worst in class" status on discontinuance. It did not do so. Although Mr Kent correctly submits that the

absence of such relative "substantial benefit" finds its way into the response to the Request for Further Information (at question 7), it is clear from the response ("*Strictly, given the answer to 6, an answer is not required*") that the assertion did not form part of the Claimants' case on defect and that the absence of substantial benefits was not therefore relevant.

g. Nor do I accept that the fact that there is or may be expert evidence to be deployed at trial which supports the Claimants' case that there is a level playing field across all the drugs in the appropriate class is relevant. This is, in any event, disputed by Mr Gibson. Further, I am told by him, and accept, that there is expert evidence which could have been deployed which would support the existence of certain benefits and indications associated with Seroxat which would make it the drug of choice for some patients. 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.

33. There is no application before me to amend the Particulars of Claim. Had one been made, I would have refused permission. It is now too late. If this claim is to proceed then it must do so on the basis of the current pleadings as analysed by Foskett J in 2016 and 2017. I accept that 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).

34. I make two final observations. The first addresses the Claimants' recurring complaint that the Defendant, having challenged the lawfulness of the approach taken to defect in the Particulars of Claim, should have launched an application for summary judgment or for a strike out. Foskett J was clear that he could as part of his case management tools have listed the issue for a preliminary hearing. He decided against this course. I too resisted the Claimants' invitation in February to rule on the point in the absence of an application by the Defendant. The Defendant has made clear in the past that it wishes the litigation to be determined, once and for all, on all issues. However, whatever, may be the reason for the absence of an application to strike out the claim, it does not seem to me to be relevant to the issue before me now, which is the scope of the claim on the pleadings. I make no ruling on the merits of the Defence case on the point. I am not invited to do so, given that this ruling on scope is a necessary prequel to any further legal argument. That said, it would be wrong for me not to acknowledge the force of the Defence submission in the light of the recent judgments of the High Court in *Wilkes v Depuy International Limited* [2016] EWHC 3096 (QB) and *Gee v Depuy International Limited* [2018] EWHC 1208 (QB) which have, in both cases, underscored the relevance of relative risks and benefits of a medicinal product when considering safety. I emphasise however that I have not heard full argument on the point.

35. Second, it seems to me that 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.