Neutral Citation Number: [2019] EWHC 337 (QB)

Case No: HX07X04076

IN THE HIGH COURT OF JUSTICE
QUEEN'S BENCH DIVISION

Royal Courts of Justice
Strand, London, WC2A 2LL

Date: 14/02/2019

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, Solicitors**) for the **Claimants**
Charles Gibson QC, Malcolm Sheehan QC, Adam Heppinstall and James Williams
(instructed by **Addleshaw Goddard, LLP**) for the **Defendant**

Hearing dates: 13 and 14 February 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 for personal injury, brought by a number of Claimants, in which it is alleged that Seroxat (the UK brand name for Paroxetine, a prescription only antidepressant and anxiolytic) is defective within the meaning of the Consumer Protection Act 1987 ("the CPA").

2. The action is listed for trial, commencing on 29 April 2019, with a time estimate of ten weeks. It has a long history. It is not necessary for me to detail all of the twists and turns of the litigation but I note that its impetus appears to date back as far as 2002 when, following a Panorama programme concerning Seroxat, a large number of users came forward claiming to have suffered serious consequences from taking the drug.

3. The first important milestone in the litigation is the Group Litigation Order ("the GLO") which was made by Senior Master Whittaker in October 2008. The GLO identified a list of 11 common, or related, issues of fact or law; this was preceded by Particulars of Claim in the case of Tracy Bishop, a lead case, which were served in December 2007. A Request for Further Information of the Particulars of Claim was the subject of a response by the Claimant in May 2008 and the Defence was then served on 15 September 2008. There followed a Reply which was initially served in May 2009 and then re-served in an amended form in April 2010. There were further pleadings including a Notice to Admit facts. The action proceeded along the usual lines with expert evidence being served and joint meetings taking place during 2009 and 2010. The litigation then came to a halt in 2010, relatively shortly before trial which had been listed to take place before Mackay J in February 2011, as public funding was withdrawn. Following this, a large number of the Claimant cohort discontinued their action leaving claims on behalf of 124 Claimants in hiatus.

4. The group litigation was restored in early to mid-2015 and the matter came before Foskett J in October 2015 for case management when the Defendant argued that the proceedings should come to a permanent halt. There were then further hearings before Foskett J at which he dealt with a range of matters. Of particular relevance to the issues for my determination today are his rulings of February 2016 and March 2017. The first pre-trial review before me took place in November 2018.

The Issue for my determination:

5. The issue before me concerns the scope of the trial. In particular, the scope of the Claimants' case on defect. There is no dispute that the Claimants' case on defect includes the assertion that Seroxat has a capacity to cause adverse effects on discontinuance such as to either prevent or make it more difficult for the user to discontinue or remain free from taking the drug to a greater extent than all other drugs in a similar class (of Seratonin Re-Uptake Inhibitors). Nor is it in dispute that the Claimants' case includes the assertion that a warning of that greater capacity to produce those adverse effects should have been included in the product literature. Both of those issues, it is agreed, are pleaded in the Particulars of Claim, are reflected in the GLO and were agreed by Foskett J to reflect accurately the Claimants' case.

6. However, in November 2018 at the PTR before me, Mr Kent QC who leads for the Claimant on this issue, flagged up that those two issues did not accurately reflect the extent of the Claimants' case on defect. To avoid the possibility of wasting time at trial determining the scope I ordered that the parties produce a list of questions/issues which they each considered should be decided at trial. The exercise has indeed demonstrated a difference between the parties, hence this ruling.

7. The Claimants' case in a nutshell is that their case on defect is not restricted to the way in which it is stated in paragraphs (a) and (d) of the GLO. The case is wider and is not solely dependent upon the Claimants establishing that, on discontinuance, the drug produces an effect which is worse than other drugs in a similar class. It is asserted that it is part of the Claimants' case, and has always been part of their case, that the severity, incidence and duration of adverse effects on discontinuance in themselves render the drug defective. In other words, the defect relied upon under the CPA is the adverse effects suffered by the user on discontinuance irrespective of the relative severity, duration or frequency of those effects when compared with other drugs in the same class. Mr Kent submits that the GLO is a non-exhaustive list of common issues. It does not trump the pleadings. The Claimants' pleaded case includes at paragraph 12 the case on the defect alleged. Paragraph 12.1 refers to the drug's capacity to cause adverse effects on discontinuance which would make the drug "*more difficult to withdraw from, discontinue or remain free from taking the product*". That allegation preceded and was independent of the further allegation which, putting it shortly, reflects the Claimants' comparative case. The pleadings do therefore embrace a case on defect which is freestanding of the relative nature of the adverse events associated with discontinuance of other drugs of a similar class. The comparative case remains part of the Claimants' case on defect but, as it was put by Mr Kent, the comparative case serves as a bolster to the other element of the case. Mr Kent accepts fully that the scope of the issues to be determined at trial was canvassed before Foskett J but he submits Foskett J never ruled formally on the topics to be covered and the scope of the issues, let alone the detail of the Claimants' case. Foskett J had no need to do so, as the lens through which he was considering the Claimants' case was, for example, the admissibility of various parts of Professor Healy's report and other ancillary matters. He never therefore confronted the scope issue in such a way as to rule upon the length and breadth of the Claimants' case.

8. There is another issue upon which I heard submissions. It concerns the risk/benefit profile of Seroxat. It arises in this way. The Defence denies the comparative, or "worst in class" case on defect as a matter of fact. It also asserts that, even if that case is established on the evidence, the Claimant should not succeed as a matter of law. At paragraph 39 of the Defence it is denied that defect within the meaning of the CPA can be established by comparing the incidence/severity/duration of a particular adverse reaction associated with Seroxat withdrawal as against the incidence/severity/duration of that adverse reaction associated with others in the class. One of the bases for this argument is that the comparison between medicines cannot be localised to a single feature, good or bad, but must include comparison of the relative risk/benefit profile generally and take into account the context of the clinical circumstances of the prescription. This is what has been described by Mr Gibson QC for the Defendant as the holistic approach.

9. Mr Kent does not accept that the Claimants' approach (the focus upon a single characteristic of a drug) is flawed as a matter of law. He does not accept that the Defendant's argument poses any particular obstacle to the claim, let alone an obstacle which will prove fatal. Although he urged me to do so, I (like Foskett J) will not rule on the merits of the defence case absent any application by the Defendant. It is a matter for me to deal with at trial.

10. 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. Mr Kent raised a pleading point. He accepts, as a matter of principle, that an analysis of the particular risks and benefits of the drug could form part of the circumstances that the Court might have regard to when considering product safety. He notes that no positive case (setting out the particular characteristics of the drug which might potentially be germane to the holistic assessment) is pleaded by the Defendant; whilst it is pleaded that Seroxat is licensed for a wide range of different anxiety related problems nothing more is said as to the potential benefits of the drug. His point to me, was that it was for the Defendant to plead a positive case on benefits and risks and not the Claimant.

11. I do not propose to set out the Defendant's responses to these issues in detail. 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. In summary, Mr Gibson submits that the Claimants' case on freestanding defect is not pleaded; it does not feature in the GLO; that when Foskett J permitted the claim to proceed, he was doing so on terms, and those terms were that the scope of the case should not be expanded beyond that which was set out in the pleadings and GLO; that Foskett J analysed the Claimants' case on defect, accurately identified the case on defect and recorded his conclusions in his two judgments of February 2016 and March 2017. Neither judgment refers to the freestanding defect. As to the risks/benefit profile of the drug, 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.

Conclusions

12. I agree with Mr Gibson that the freestanding defect is not in scope for the following reasons:

    a. the high point of the Claimant's case is paragraph 12.1 of the Particulars of Claim. That paragraph refers to the adverse effects on discontinuance making it "more" difficult for the user to withdraw from usage of the drug; even within this assertion is an implicit comparison as to the ease of discontinuance with other drugs.

b. I also note the way in which the case is pleaded at paragraph 5.1 where the Claimants set out their generic case on defect:

"*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"

c. The GLO makes no reference to the freestanding defect now alleged. Critically, the GLO reflected the agreed list of issues of fact and law at the time of the adjourned trial before Mackay J.

d. Foskett J set out the Claimants' case on defect in clear terms: in the February 2016 ruling at [5] and [7]. At [58] of the same judgment he records that Professor Hotopf (an expert instructed by the Claimant) "*explained to the new legal team that his changed position still supported the main thrust of the case that the adverse effects of the drug were "worst in clas*s."

e. Foskett J, in his judgment of March 2017 (and perhaps because of his sense that there was some attempt by the Claimant to expand their case) repeated at [11] the essential nature of the case advanced on behalf of the Claimants' and expressed his belief that his summary was "*common ground*" At [20] he observed: "*since close of pleadings it has been plain that the Claimant's case proceeds <u>only</u> on the basis of what can be described as a worst in class for discontinuation symptoms for SSRIs allegation and the associated allegation of a failure to warn that Seroxat was "worst in class" in this respect*". It does not seem to me that Foskett J could have been any clearer as to his understanding of the Claimants' case on defect.

13. My analysis of the issues raised in the pleadings accords with that of Foskett J. Further, Foskett J was not exercising a purely case management role at the hearings in February 2016 and March 2017, at least not in the usual sense. The issue which Foskett J was grappling with was whether the case should be revived at all in 2015, after a 5 year hiatus. He was required to make his ruling in the face of powerful arguments deployed by the Defendant that he should not do so. He sought to strike a fair balance between the parties. The balance came down in favour of permitting the claim to proceed, but only on the basis of the case as advanced by the Claimants in 2010 when it was stayed. It seems to me that in those circumstances, I should in any event be very slow to disturb his decision and expand the scope of the trial. I also add that I am informed by Mr Gibson that if the scope of the proceedings were to be expanded, the Defendant would be prejudiced as there would be insufficient time to embark upon examining and meeting a broader case than that pleaded. I accept this.

14. My ruling is therefore that the Claimant's case on defect is restricted to that reflected in the GLO and does not include the freestanding case based upon the incidence, severity and duration of adverse events upon withdrawal from the drug.

15. I move on then to the risks and benefits issue. As I have said, 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.

16. I do not accept Mr Kent's point that the Defendant was, for some reason, required to plead a positive case on benefits. The Claimant clarified its case on defect in a Reply to a Request for Further Particulars dated 23 May 2008. The question was posed by the Defendant: "*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?*" The response given by the Claimants was an unequivocal "No". In other words, by the response, the Claimants were making the point that their case on defect (based on the relative severity of adverse events on discontinuance of Seroxat) was independent of, and irrespective of, any benefits, relative or otherwise that the drug might confer on a user. Given this response, it seems to me that, as a pleading issue, the Defendant was entitled to meet the Claimants' case in the general way in which it did. It would be different if the Defendant was intending to advance a positive case at trial and rely upon particular benefits associated with Seroxat which were not shared by others in the class. But it has not done so. Likewise, if the Claimants had responded in a different way and asserted that relative benefits were relevant to its case on defect then I can see that such a response might have put the ball into the Defendant's court. But that was not the response.

17. 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.

18. As to the other matters for my ruling, I allow the Claimants' application that the lead case of Mr Holmes should be added, as an additional case to those already agreed between the parties. There will therefore be 5 lead cases. As to the admissibility of a number of sections in Professor Healy's joint note, some agreement concerning the various passages identified by the Defendant has been possible. In approaching those few passages which remain the subject of dispute, I remind all involved in this litigation that the Defendant's conduct is of no relevance to the issues which I will need to determine at the end of the trial. Evidence which impugns the Defendant's conduct should not be given. No doubt all experts will respect this injunction. In respect of the offending passages, it is relevant for Professor Healy to comment that there may be various factors which impact upon the value of various studies: for example, the particular design of a study, the data which was inputted to the study and the fact that those who write up such reports may not have access to the raw data. To go further than this and to suggest that, in some way, the Defendant has sought to influence the trial outcome is impermissible. With this in mind, I direct that the highlighted sections in the fourth paragraph on page 3 of the joint report, the final paragraph on page 3

(going on to page 4) of the report and that on page 20 of the report should be redacted. It seems to me that those sections cross the line between what is relevant and what is not. They may also open up contentious issues of fact which will not be resolved at trial.