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Don't go changing your claim: High Court and Court of Appeal rule on preliminary issue of the scope of the claimant's claims on defect in the seroxat group litigation

Introduction

On 8 November 2019, the Court of Appeal handed down a unanimous decision on an important preliminary issue in the case of Bailey and others v GlaxoSmithKline [2019] EWCA Civ 1924. The decision upholds the 9 May 2019 judgment of Lambert J in favour of the Defendant and is the latest episode in the long-running saga of the Seroxat group litigation – a dispute for which proceedings were first issued in 2007. As outlined below, the Court of Appeal held that the Claimants' case that Seroxat was defective had to remain limited in scope to the argument that Seroxat was "worst in class" regarding the drug's withdrawal symptoms. The Claimants were not permitted to extend the parameters of their case by asserting that Seroxat has no relative benefit over comparator drugs, as this assessment of Seroxat's risk-benefit profile had not been included in the Claimant's initial pleadings.

Background

The Seroxat litigation was originally brought by a group of claimants in 2007, who alleged that Seroxat, a prescription-only antidepressant and one of a class of Selective Serotonin Reuptake Inhibitors ("**SSRIs**") manufactured by the Defendant, was defective within the meaning of the UK Consumer Protection Act 1987 ("**CPA**").[49] Among other things, the Claimants alleged that Seroxat was defective in that it had the capacity to cause adverse effects when discontinued, which prevented or made it more difficult for users to discontinue the drug as compared to other SSRIs.[50]

In 2008, the Defendant issued a Request for Further information to check whether it was part of the Claimants' case that the benefits of Seroxat as compared to other SSRIs were to be taken into account. The Claimants responded in the negative, noting that in the event potential benefits were determined to be of relevance, the Claimants would deny Seroxat had any greater effectiveness or substantial benefit compared to other SSRIs.[51] The Defendant pleaded in response that the Claimants' approach to defect was flawed, as 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 the particular claimant in question. The Defendant also challenged the Claimants' case on the facts (i.e. disputing that Seroxat caused greater adverse effects on discontinuance).

The claim was effectively stayed from 2010 to 2015 due to funding issues experienced by the Claimants. Following this, in 2015 case-management judge Foskett J was tasked with determining whether the resumed action should be allowed to proceed given the prolonged interval before it returned to court. In a series of case-management decisions, Foskett J held that fairness dictated that the litigation be allowed to continue, so long as the Claimants' case remained as pleaded at the date of the vacated trial. As stated by Foskett J, a "*risk/benefit analysis had been expressly disavowed*" when setting out the Claimants' pleaded case.[52] The fresh trial commenced in the High Court before Lambert J in April 2019.

The decisions by the High Court and Court of Appeal

During opening submissions at trial, the Claimant invited the court to infer a "*level playing field*" between Seroxat and other SSRIs, save for the single product characteristic (the greater adverse effects on discontinuance) said to constitute the defect. The Defendant's challenged this, stating it required and the inference that Seroxat had no particular benefits compared to other SSRIs, which went beyond the Claimant's pleaded case. The issue had to be determined before the trial could continue.

49 Section 3 of the CPA states that a product will be deemed defective "*if the safety of the product is not such as persons generally are entitled to expect*". Section 3(2) then states that in determining what persons generally are entitled to expect "*all the circumstances*" shall be taken into account, and sets out a list of non-exhaustive factors required to be taken into account.

50 As quoted at paragraphs 9 and 10 of *Bailey and others v GlaxoSmithKline* [2019] EWCA Civ 1924

51 As summarised at paragraphs 11 and 12 of *Bailey and others v GlaxoSmithKline* [2019] EWCA Civ 1924

52 As quoted by the Court of Appeal at paragraph 37 of *Bailey and others v GlaxoSmithKline* [2019] EWCA Civ 1924.

The High Court agreed. In a judgment dated 9 May 2019, Lambert J noted that the opportunity had been open to the Claimants back in 2008 to amend their pleadings so as to include consideration of Seroxat's relative benefits and risks, but the Claimant had not chosen to do so. Further, the Claimants had made no attempt to appeal the case management rulings of Foskett J which had both delineated the scope of the claims allowed to proceed and established the limits of expert evidence to be adduced based on this scope. As to the Claimants' argument that the Defendant had not put forward a *positive* case on the benefits of Seroxat compared with other drugs in the comparator group, Lambert J held that the Defendant was under no obligation to put forward a positive case where the Claimants' had not pleaded a lack of such benefits to begin with. As such, the Defendant's failure to do so did not amount to a concession that no such benefits existed.

The Claimants appealed, pointing out that Foskett J's rulings were given at a Case Management Conference ("**CMC**") where he was not specifically asked to rule on the question of whether the Claimants were entitled present a risk/benefit case. The Claimant's argued that as the orders made following those CMCs contained no such decision, there was therefore no order made which could have been appealed. As such, the Claimants' position was that Lambert J had erred in her interpretation of Foskett J's judgment.

The Court of Appeal disagreed, holding that Foskett J had clearly identified the issues for trial and set out how the case was to be case managed going forward, including a statement that he would not permit any expansion of the case outside of the parameters he defined. The Court of Appeal's judgment quoted extensively from, and approved Lambert J's judgment, concluding that it was "*plainly impermissible*" for the Claimants to seek to raise the risk/benefits case in opening their case at trial. In particular, raising such arguments now would raise a wide ranging factual and expert inquiry on the relative risks and benefits of Seroxat, which the parties had not carried out.

Comment

The Court of Appeal's ruling is a useful reminder to litigating parties of the importance of case management decisions within UK proceedings. The Court of Appeal emphasised that good case management involves identifying lists of issues which direct the scope of disclosure and the preparation of factual and expert evidence. As such, departing from or seeking expansion of, the clearly delineated issues would undermine the principle of careful and efficient advance management. This is particularly important when managing large group actions.

From a product liability perspective, the Court of Appeal's decision is significant in that it adopted the High Court's decision of *Wilkes v DePuy International Limited* [2018] QB 627[53] and in particular the finding of Hickinbottom J that "*assessment of whether the safety of a product is at an acceptable level requires a holistic approach*".[54] This marks the first time the Court of Appeal has endorsed the holistic approach to defect. Elsewhere, the High Court had already followed this approach in *Gee v DePuy International Limited* [2018] EWHC 1208 (QB).

The case also serves as a reminder to claimants precisely to outline the defect alleged when bringing CPA claims. As stated by the Court of Appeal, it is this articulation of defect that will drive the scope of expert evidence and the focus of the trial, rather than the Defendants response.

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53 Further discussion of the case of *Wilkes v DePuy International Limited* can be found in issue 65 of the International Product Liability Review, December 2016

54 As quoted by the Court of Appeal at paragraph 8 of *Bailey and others v GlaxoSmithKline* [2019] EWCA Civ 1924.