Product liability update

May 2019

Sandra Bailey & Ors v GlaxoSmithKline UK Ltd (2019)

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"No deal" Brexit: Changes to the Product Liability and Safety Legislation

On 25 March 2019 the Government published guidance on the potential changes to product safety legislation in the event the UK leaves the EU without agreement on its terms of exit. more›

Any comments or queries?

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Sandra Bailey & Ors v GlaxoSmithKline UK Ltd (2019)

The trial of this long running group litigation started on 29 April 2019 and is listed for 10 to 12 weeks. It involves an action for damages from a large number of Claimants, arising from their use of the drug, Seroxat (a prescription only antidepressant), which is alleged to be defective under s3 Consumer Protection Act 1987.

The litigation has a long history, the Particulars of Claim having been drafted as long ago as 2007.

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.

An urgent issue arose during the Claimants' opening at trial concerning the scope of their 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 submitted that the Court should assume "a level playing field" 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 submitted that this inference or assumption arises from the parties' respective formal statements of case. This was disputed by the Defendant who argued that this was not the case that had been pleaded by the Claimants.

Mrs Justice Lambert held that the Claimants are not entitled on the position as set out in their statement of case 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", as this was not consistent with the pleaded case.

The judge went on to hold that since the Claimants had 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 the analysis of 'defect' was flawed. 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 other drugs of a similar pharmacological make up, but had chosen not to do so. The fact that it did not do so was not a concession that no such benefits existed.

No application to amend was made. However, had there been such an application, Mrs Justice Lambert would have refused permission on the basis that it was too late.

This decision it useful for Defendants in the event that a Claimant attempts to raise issues at trial which have not been pleaded, or have been improperly pleaded, and provides a useful reminder to Claimants to ensure that their case is pleaded precisely in the matter they intend. It is not for Defendants to put forward a Defence to matters not so pleaded and a Defendant should not be expected to infer what a Claimant's case might be.

The trial continues.

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Consultation on food labelling

The Food Standards Agency (FSA) has recommended to the Government, as part of the Government's consultation upon proposed changes as to how allergen information is to be given on prepacked foods, that food outlets be obliged to list all ingredients in order to protect customers with allergies.

FSA chairwoman Heather Hancock said the FSA had chosen the strictest of the options they had under discussion because "ultimately this is a life-threatening issue for a proportion of the population".

The FSA board discussed several options, ranging from light-touch intervention of promoting best practice in the food industry to requiring businesses to list the 14 most common allergens.

Some objections to the proposal include an argument that it would push up costs. There are also fears that some businesses might refuse entirely to serve people with allergies if new rules introduced are too onerous.

The Department for Environment, Food and Rural Affairs (DEFRA) will have the final say over whether new rules are introduced.

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Increasing concern about the rise in counterfeit goods

The revolution of the internet has brought progressive and positive changes to society, one being e-commerce. Consumers are increasingly buying goods online due to convenience as well as product variety.

However, this development has also led to the rise in sales of counterfeit goods. In the 2018 Global Brand Counterfeiting Report it was estimated that the total value of counterfeit products across the world would reach $1.8 trillion by 2020. Local Circles conducted a survey which found that 38% of the consumers who completed the survey had received counterfeit goods from online sites.

This issue is evidently causing concern in the e-commerce market. In February 2019, Amazon launched Project Zero which aims to tackle the counterfeit problem. This project will allow brands to use its self-service counterfeit removal tool to delete rogue products. Amazon will also use an automated system which scans logos and trademarks on its website in order to help confirm whether products on sale are genuine.

The expansion of the counterfeit market is also occurring in the drugs industry. It has been reported that since 2015 at least 204 deaths have been linked to counterfeits of the drug Xanax, the trade name of Alprazolam, which is used to treat anxiety and panic disorders. Worryingly, the value of the counterfeit market of this drug amounts to £1 million in the UK alone.

Similarly, there is an increasing amount of counterfeit electrical products and components being sold, raising serious concerns regarding fire safety, as was first highlighted in 2015 in a report by the charity Electrical Safety First. Despite a subsequent parliamentary debate, there has been little progress since 2015.

The growth in the counterfeit market is clearly a major problem for brands and consumers alike, but it is also worrying for insurers. Insurers should be concerned with the consequential claims which faulty products can cause, such as fire claims on household and building policies, and claims on life insurance policies. Moreover, Insurers should be aware that they could be facing product defect claims when it cannot be proved that the product is in fact a counterfeit, for example in the case of electrical goods destroyed in the fire they caused.

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"No deal" Brexit: Changes to the Product Liability and Safety Legislation

On 25 March 2019 the Government published guidance on the potential changes to product safety legislation in the event the UK leaves the EU without agreement on its terms of exit.

Parliament has approved a number of statutory instruments which come under the name of the Product Safety and Metrology etc (Amendment etc) (EU Exit) Regulations 2019.

The proposed legislation, which is awaiting ministerial approval before taking effect, will apply changes to the current Consumer Protection Act 1987 ("CPA") and General Product Safety Regulations 2005, amongst other domestic product safety statutory provisions.

The CPA defines importers as being importers of products into other EU countries. The proposed amendment changes the definition to refer to importers into the UK. Similarly, the definition of producer in the General Product Safety Regulations will be limited to those producers established in the UK.

Currently CPA s4(1)(a) provides a statutory defence in case a product is defective, if the defect is attributable to compliance with "any requirement imposed by or under any enactment or with any EU obligation". Under the proposed legislation, this would only extend to UK enactments or any retained EU legislation.

In order to maintain conformity with the standards and the rules in question, the proposed legislation would see the Secretary of State take over the responsibility to publish standards and guidelines. In addition, as reported in our February 2019 update, new UK Conformity and Assessed marking (UKCA) will be used for carrying out conformity assessment of products currently subject to CE marking. Furthermore, all Notified Bodies currently operating in the UK will become UK Approved Bodies. The Department of Business, Energy and Industrial Strategy (BEIS) has put together a register of those Approved Bodies.

In the event that a product represents a serious risk and is recalled, withdrawn or prohibited on the market, the market surveillance authorities must inform BEIS as the EU RapEX (rapid alert system) database will no longer apply to the UK.

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