HENDERSON CHAMBERS

Product Liability update in the UK/emerging risks

Introduction

1. Directive 85/374/EEC was implemented in the UK by Part 1 of the Consumer Protection Act 1987 ("the CPA").

2. Many believed this heralded a new dawn in product liability litigation in that it would open the floodgates to mass tort claims.

3. In the decade following the CPA there were no reported cases under the Act. This was because unitary claims usually settled and the large group actions often collapsed due to withdrawal of public funding.

4. Then in the 12 months between December 1999 and December 2000 there were a flurry of 4 first instance decisions Worsley v. Tanbrands Limited (toxic shock from a tampon), Richardson v. LRC Products Limited (split condom), Foster v. Biosil (ruptured breast implant) and Abouzaid v. Mothercare (dangerous strap on pushchair blanket). In the first 3 cases the claimant failed, in the last the claimant succeeded.

5. This was followed in 2001 and 2002 by decisions in group action CPA claims – the hepatitis C blood contamination claim, oral contraceptives and the modest group action of Bogel v. McDonalds Restaurants Limited. The claimant succeeded in the Hep C case but failed in the other 2 cases.

6. From 2002 there was another lull in terms of reported decisions but other substantial cases (e.g. MMR and Organophosphate) were progressing.

The Hep C case

7. This is the case which involves the most detailed analysis of the Act by Burton J. The litigation concerns the claims of 14 claimants for recovery of damages arising out of their infection with the Hep C virus from blood and blood products through blood transfusions. The essential question was whether blood supplied through the National Blood Transfusion Service which was infected was a defective product.

8. It was accepted by the claimants that the virus itself had not been identified by the 1st March 1988, that screening tests against such a virus were not available, and that the NBA were not negligent in failing to have a screening test. But the claimants said that the legitimate expectation of people generally was that transferred blood would not infect patients with Hep C and that the conduct of the producer was irrelevant. Questions of avoidability of the defect, practicality of its avoidance and economic feasibility were not factors to be taken into account in determining the safety of the product.

9. The defendants contended the risk of infection with Hep C was known to the treating doctors avoidability or unavoidability were relevant factors and the legitimate expectation of persons generally was not that blood would be 100% clean but that all legitimately expected and reasonably available precautions had been taken.

10. Burton J approached the question of defect in the following way:

    (i) The purpose of the directive was to increase consumer protection, which it did by introducing an obligation on producers irrespective of fault.

    (ii) It is for the court to determine what persons generally were entitled to expect.

    (iii) Avoidability, practicality and other such matters are irrelevant otherwise you are introducing negligence by the backdoor. The public at large were entitled to expect that the blood transfusion would be free from infection.

11. As to development risk –

> *"It is a defence to show –*
>
> *(e) that the state of scientific and technical knowledge at the time was not such that a producer of products of the same description as the product in question might be expected to have discovered the defect…."*

Burton J held that this defence should be construed strictly. Its purpose, he said, was to protect the producer in respect of the unknown generic defect but not in respect of a known but undetectable generic defect.

12. When this decision is coupled with the decision of the Court of Appeal in Abouzaid on the development risk defence, its scope appears very narrow. In Abouzaid the Court of Appeal held that provided the manufacturer could have discovered (i.e. it was feasible to discover) the particular defect, the defence was not available. But there was no detailed analysis in the Abouzaid case.

Bogel v. McDonalds

13. Field J considered the claims of McDonald's customers who were scalded by cups of hot tea and coffee.

14. In dismissing the CPA claim Field J adopted the approach set out by Burton J and concluded that the safety of hot drinks met legitimate expectations of persons generally.

    (i) The polystyrene cups holding the drinks were sarong enough to hold the contents.
    (ii) The serving staff were trained and one of the matters included in the training was the capping of hot drinks securely.
    (iii) The great majority of likely customers could be expected to know the tea and coffee served was hot and would cause a serious scalding injury if spilled.
    (iv) Persons generally expect such drinks to be hot and whilst they expect precautions to be taken to guard against the risk of spills not to the point that "they are denied the basic utility of being able to buy hot drinks to be consumed on the premises from a cup with the lid off."

15. Whilst the approach adopted purported to follow the Burton analysis it is instructive that in considering whether the product was safe the Judge delved into details of what the producer had done to ensure that the staff were properly trained. This is a very similar analysis to the sort of analysis that would be undertaken in answering the question, was the defendant negligent.

Recent decided cases

16. **Palmer v. Palmer & Others [2006] All ER D86.** In this case the High Court examined the meaning of defect under the CPA in relation to a product that had a tendency to induce misapplication. In other words whether a product's potential for being misused is sufficient to render it defective under the CPA. Palmer concerned a clunk-clip seatbelt slackening are "after market device" that is not provided as part of the original equipment by car manufacturers. The injury to the claimant, a child, had been caused by excessive slack in the seatbelt which had been introduced by the device not having been correctly used.

17. The device had been on the market since the late 1970s and had been favourably tested by an expert. The finding of the court, however, was that the device had a tendency to induce some members of the public to introduce excessive slack into the belt particularly given that the instructions were incomplete in failing to warn of the need to disengage the device before fastening the seat. The product was therefore found to be defective under the CPA.

18. **Piper v. JR Manufacturing Limited [2006] EWCA Civ 1344** – in this case the Court of Appeal looked at the statutory defence under section 4(d) that the product was not defective when it left the control of the manufacturer. A prosthetic hip was implanted into the claimant which failed prematurely, causing the claimant to undergo a further operation and reducing his mobility. The Judge made a finding of fact that the prosthesis was not defective at the time it was supplied to the hospital. It was necessary therefore to go on and decide how or when the surface point defect which initiated the fatigue failure arose.

19. **Pollard v. Tesco Stores Limited & Others [2006] EWCA Civ 393** - the cap of a dishwasher powder bottle claimed to be compliant with British Standard torque levels for child resistant closure. BS compliance was not a legal requirement. Although the bottle was easier to open than a BS level cap, the fact that it still had some level of "child resistance", meant that it was not defective under the Act, even when a 13 month old child consumed part of the contents. Violation of a voluntary product standard does not lead to a conclusion that a product is defective.

20. The Court of Appeal's approach in Pollard was a pragmatic, commonsensical and broad brush approach to the CPA which is more in keeping with the earlier first instance decision in Worsley, Richardson, Foster and Bogel and in sharp contrast to the more purposive and policy based approach of Burton J in National Blood.

21. There can be no doubt that an analysis of these cases as so often emphasises the need to look closely at the facts and the nature of the product in question. Hep C was a hard case on the facts.

Limitation under the CPA

22. Under the CPA 1987 a claim is extinguished after the expiry of 10 years from the date when the product was put into circulation. This has given rise to two important issues. When is the product put into circulation and can a defendant manufacturer be substituted as a defendant on an application of English procedural rules after the 10 year long stop expired.

23. In **O'Byrne v. Sanofi Pasteur MSD** the claimant had suffered brain damage as a result of an allegedly defective vaccine. His solicitors brought an action against the wrong defendant and only realised their mistake, and sought to substitute the correct defendant, after the 10 year long stop period had expired. The case was referred to the ECJ held that a product was put into circulation when it entered the marketing process in the form in which it is offered to the public in order to be used or consumed. That is the date from which the 10 year long stop runs. However they also held that it is open to an National court in the exercise of its procedural rules to allow the substitution of a defendant after the expiry of the 10 year long stop.

24. The case was referred back to the High Court and then the Court of Appeal who held that a party could be substituted under s. 35 of the Limitation Act 1980 in these circumstances, even where the correct party was known to the claimant before the limitation period expired, *if* the claimant had made a mistake about the name of the defendant and substitution was necessary for the purpose of determining the original action.

Current cases going through the Courts

25. There are currently a number of cases being partly funded by the Legal Services Commission which are going through the courts.
    (i) The Sabril litigation involving an anti-epileptic drug.
    (ii) The foetal anti-convulsant litigation.
    (iii) The Seroxat litigation.

The key unanswered question in pharmaceutical litigation

26. In each of the above cases currently being progressed through the Courts the key unanswered questions will be addressed if the cases proceed to trial. In summary: How should questions of defect and development risk be interpreted in the context of pharmaceutical products which are the subject of regulation?

27. **Defect** - claimants argue that a drug is defective if the claimant suffers from an unwarned against side effect. On this analysis each time the warnings are changed the drug will automatically be defective prior to the change. The counter-argument for this is that persons generally are entitled to expect the drug company to ensure that its warnings are at any given time appropriate. But that does introduce notions of reasonableness which on a Burton J analysis of defect should be irrelevant. This issue has not been decided.

28. **Development Risk:** The claimants contend that the strict definition of defect is mitigated by the development risk defence. However, they then adopt the strict Hep C/Abouzaid approach to development risk and contend that provided the particular harmful characteristic was discoverable the defence is not available. Thus a drug company which carries out exhaustive toxicological trials and clinical trials and reasonably concludes (along with the regulatory authorities) that the drug is safe will have no defence if they could have discovered the defect i.e. it was feasible to do so even if no one at the time reasonably concluded that it was necessary or appropriate to pursue a particular line of scientific enquiry. The defendant's response to this argument, in a nutshell, is that when considering the development of knowledge it is necessary to have regard to whether the defendant could reasonably have discovered

the harmful characteristics. This is particularly important if a stricter definition of defect is to be applied.

29. This unresolved issue is of critical importance to the pharmaceutical industry.

Emerging Risks

Key areas

30. Key areas for consideration of emerging risks in addition to pharmaceutical claims which we have already considered include:
    (i) European Group Actions and increasing amounts of "safety" legislation and regulation.
    (ii) Group actions in the England – LSC funding is tight but there are increasingly innovative ways for consumer groups to obtain funding.
    (iii) Alcohol related claims.

31. As to the legislation, the European Commission has recently confirmed that Directive is not in need of amendment because it is adequately balancing the needs of consumers and manufacturers.

32. The new EU General Product Safety Directive came into force in the UK in 2005. This Directive has brought an end to silent recall of consumer products. In future producers and distributors require to notify authorities of any risks, and National authorities have new powers and obligations to enforce the product safety laws and prosecuting those failing to meet their obligations. National authorities also have powers to initiate product recalls of their own accord.

33. On 1st January 2005 the general framework law on food safety and hygiene came into force. The law focuses on 3 areas:
    (i) Food and feed safety – traceability, safety, withdrawal of unsafe foods, notification, labelling.

(ii) Health and nutrition information – labelling, provision of nutritional information and regulation of health and nutrition claims.

(iii) Food hygiene measures, registration, hazard analysis, supervision/ instructions/ training.

34. At a National and Europe wide level there is a trend within the EU towards legislation promoting representative actions in consumer protection legislation. I do not foresee US style class actions taking off in this country or in Europe. The European Union is currently looking at further ways of enabling groups to obtain collective redress and there is a great deal of activity in this area at present but no concrete proposals are imminent.

35. The DTI in the UK is currently consulting about how representative actions on behalf of consumers can more easily be brought. I don't myself think that any changes are necessary.

Alcohol claims

36. Alcohol manufacturers are facing similar questions to those faced by the tobacco industry some years ago. It would once have seemed bizarre to suggest that warnings ought to be placed on alcohol beverages but that is now increasingly the norm. Alcohol manufacturers are also actively promoting "sensible" drinking. As concerns about binge drinking and under age grow so does the potential for litigation particularly with the increasing popularity of certain "mixer" drinks.

37. In the UK and Europe, so far as I am aware, there have been no successful product liability alcohol claims. Alcohol claims have been brought in the US for many years but no claimant has succeeded against a drinks manufacturer.

38. The position is different when considering potential causes of action leading to claims on employers' liability insurance. This is most likely to arise where the consumption of alcohol by an employee has led to behaviour which has caused accidental personal injury to the employee, a fellow employee or a third party.

39. There have been a very limited number of civil cases in the United Kingdom which have addressed the liability of employers for alcohol related claims. Those that have been considered in the UK or overseas have arisen from one or more of the following factual circumstances:

(i) The supply of alcohol to employees by the employer, the provision of facilities for employees whom the employer knows will be drinking, the monitoring of alcohol consumption and provision of treatment to employees affected by alcohol. In a recent case called Geffson re Ministry of Defence Potter LJ stated *"the law recognises that there may be circumstances in which by reason of drunkenness or other factors foreseeably likely to affect an adult's appreciation of danger he may act in a childish or reckless fashion, and that in appropriate circumstances there may exist a duty on others to make allowance for those actions and take predations for the perpetrator's safety."*

(ii) In short, the duty will be limited to the taking of reasonable steps to prevent employees being injured as a consequence of their drunkenness. Employers will also need to have policies in place where their employees' performance can be significantly affected by alcohol consumption.

CHARLES GIBSON QC

PRASHANT POPAT

20th November 2007