OUTER HOUSE, COURT OF SESSION

[2018] CSOH 109

A300/14

OPINION OF LORD BOYD OF DUNCANSBY

In the cause

GR

Pursuer

against

(FIRST) GREATER GLASGOW AND CLYDE HEALTH BOARD AND
(SECOND) JOHNSON AND JOHNSON MEDICAL LIMITED

Second Defenders

Pursuer: Milligan QC, Connolly; Lefevres
First Defender: No Appearance
Second Defender: Currie QC, Smart, Paterson; Clyde & Co (Scotland) LLP

27 November 2018

[1] This is another of a large number of cases involving vaginal mesh products. I heard a debate in four related actions in December 2017 (*AH* v *Greater Glasgow Health Board* [2017] CSOH 57). Two of these cases involved Johnson & Johnson Medical Limited (Johnson & Johnson), the second defenders in this action. In both cases the pursuer's case against Johnson & Johnson was based on an alleged breach of the Consumer Protection Act 1987 and a breach of their common law duty of care to the pursuer. After Mr Currie, who appeared for Johnson & Johnson in that debate, had spoken Mr Milligan informed the court that he no longer insisted on the common law case. In due course I allowed a proof before

answer restricted to the case under the Consumer Protection Act 1987. The decision is being reclaimed.

[2] There are however a number of cases which are based only on an alleged breach of common law duty. It transpired that Mr Milligan's concession only applied to the cases being then debated and not to cases which rely only on the common law case. Subsequently I granted a motion to debate this case to give guidance on the cases which rely solely on the common law.

[3] The pursuer was born on 3 December 1946. She had longstanding problems with stress urinary incontinence (SUI) and urge incontinence. She was referred by her GP to a consultant at the Southern General Hospital in Glasgow in 2002. Initial treatment involving physiotherapy and anticholinergic medicine did not assist. Following surgery in 2003 she was advised to undergo a new procedure to address her SUI. On 17 February 2004 she underwent surgery during which a mesh implant was inserted. The device was a Gynecare TVT manufactured by the second defender and supplied by them to the Southern General.

[4] The pursuer says that immediately after surgery she suffered in a number of ways. These are set out in condescendence 20 and I reproduce the salient points below.

[5] The first defenders, Greater Glasgow Health Board, are said to be vicariously liable for his acts and omissions of the doctor who carried out the surgery. The case against the doctor is the same as that against the doctors in *AH.* No issue concerning the first defenders arise in this debate which was restricted to the second defenders' second plea in law and the first defenders did not appear.

[6] The issue in this case is whether or not the pursuer has pled a relevant case at common law against the second defenders.

Pleadings

[7] For ease of reference I reproduce the pleadings which are the focus of attention. The relevant parts of condescendence 4 are as follows;

> Prior to the 1990s synthetic mesh was avoided for treatment of SUI or pelvic organ prolapse (POP) because of the recognised complications of fibrosis and erosion seen with Mersilene and Gore-Tex slings. In around 2002, the second defenders began to market and sell a product known as Gynemesh, for the treatment of medical conditions in the female pelvis such as stress urinary incontinence. Gynemesh was derived from a product known as Prolene Mesh which was also used for treatment of such conditions. In around 2005, the second defenders began to sell and market a product known as TVT for the treatment of stress urinary incontinence in women. The TVT has been and is offered in multiple variations including TVT, TVT-O (as used on the pursuer) and TVT-S. All of the aforementioned are hereinafter referred to as Pelvic Mesh Products. All of these Pelvic Mesh Products are made from polypropylene. Polypropylene is not a suitable substance for a permanent prosthetic implant in the pelvic region because (1) the pores are too small; (2) it is heavy weight mesh; (3) it degrades over time; (4) it causes chronic foreign body reactions, fibrotic bridging, mesh contracture/shrinkage, fraying, particle loss, sharp edges, roping and curling of the mesh; (5) it deforms; (6) it is cytotoxic; and (7) the pores collapse with tension. The Manufacturer Safety Data Sheets for polypropylene resin used to manufacture these Pelvic Mesh Products warned against the use of mesh in permanently implanted medical devices.

[8] There then follows some further specification of problems said to be associated with polypropylene and reference to a number of studies published in 2010 and 2012. The pursuer avers that mesh is not inert but degrades and elicits a continuous immune response. Degradation needs to be studied further. The condescendence continues;

> The second defenders' Pelvic Mesh Products were designed, patented, manufactured, labelled, marketed, and sold and distributed by them. These pelvic mesh products were placed on the market with little or no clinical data from adequately powered randomised studies. There is still very little evidence in relation to mid and long term safety and efficacy. Despite this, manufacturers promote the products as safe, effective and easy to implant.

[9] The relevant parts of article 5 are in the following terms;

> Contrary to their representations and marketing, the second defenders' pelvic mesh products carry with them a number of serious risks and defects. Reference is made to Article 4 of Condescendence. The second defenders do not provide adequate warnings of these risks, either to doctors or to patients. The second defenders have

known of these risks since at least 1988. With proper testing of their products before putting them on the market, they would have known of those risks even earlier. They marketed the Gynecare TVT product without designing a safe and effective procedure for removal of the Pelvic Mesh Products. ……. The injuries, conditions and complications suffered due to Gynecare TVT insertion include but are not limited to, mesh erosion, mesh contractions, infection, fistula, inflammation, scar tissue, organ perforation, dyspareunia, blood loss, neuropathic and other acute and chronic nerve damage and pain, pudendal nerve damage, pelvic floor damage, pelvic pain, urinary and faecal incontinence, prolapse of organs.

[10] The averments of fault against the second defenders are to be found in article 19;

Separatim, the second defenders' actions were negligent at common law. The pursuer's loss, injury and damage was caused or materially contributed to by the fault of the second defenders. As hereinbefore condescended upon, the second defenders manufactured and sold Pelvic Mesh products, to be surgically implanted in patients such as the pursuer. They manufactured the product. The purpose for which the TVT was commonly acquired was for the TVT purpose hereinbefore condescended upon. The second defenders had a duty to exercise reasonable care in the design, manufacture, marketing and supply of their products. They knew of the purpose to which the TVT product was to be used. They designed and manufactured the TVT for that purpose. They marketed, promoted and supplied the TVT as reasonably fit for that purpose. They were aware that the purposes for which the TVT was commonly supplied and acquired and the purpose for which it was to be used on patients such as the pursuer was the TVT purpose. They had a duty of care in such circumstances towards patients such as the pursuer to take reasonable care that the product was safe for surgical use, and would not cause further injury to patients such as the pursuer. In said duties, the second defenders failed and so caused or at least materially contributed to the loss, injury and damage suffered by the pursuer. It was their duty to take reasonable care not to supply to hospitals a product they knew or ought to have known was untested for efficacy and safety. The second defenders failed to adequately test their TVT products (including the TVT product) before supplying, distributing marketing or promoting them in the UK. They failed to conduct any adequate clinical or other experimental studies of their TVT products before supplying distributing, marketing and promoting them in the UK. They failed to carry out any or any adequate long-term post market testing and post market surveillance in relation to their TVT products. In all the circumstances, the second defenders failed in their duty of care to the pursuer and so caused or at least materially contributed to the loss, injury and damage suffered by the pursuer. The second defenders knew that the product was untested; that there were reports of adverse events and failure; and it was accordingly their duty to withdraw the product from the market, or, if they decided not to do so, to take reasonable steps to ensure that patients were made aware of the risks. That could have been achieved by producing patient information leaflets for handing to patients, or publication of warnings in the popular press. The second defenders did not take any such steps. Had they done so, and the pursuer been made aware of the lack of testing and the growing number of complaints about the product, she would

not have permitted it to be included in her surgical procedure. Had the second defender not failed in their duty to the pursuer she would not have suffered the loss, injury and damage hereinafter condescended upon.

[11] The injuries which the pursuer is said to have suffered are set out in article 20

> As a result of the … second defenders' fault and negligence at common law …..the pursuer has suffered loss, injury and damage is entitled to damages therefor. Separatim, the pursuer suffered pain following her surgery in 2004. Immediately after her surgery the pursuer was in severe pain with abdominal cramps. She was absent from work for 2-3 weeks. The pain reduced after approximately 2 weeks and then recurred. She continues to experience pain on a regular basis and this has interfered with both her working and social life. Following implantation of the TVT the pursuer again experienced urinary incontinence and from lethargy. The pursuer is unable to have sexual intercourse with her husband. The pursuer is no longer able to pursue her hobbies of tennis, aerobics or dancing. She continues to experience muscle pain in her back and legs, urinary tract infections and cystitis. She suffers from abdominal cramping and sharp pains and takes ibuprofen regularly.

Submissions

[12] Both parties made written submissions and spoke to them in oral submissions. They can be briefly summarised as follows.

[13] Mr Currie submitted that the pursuer could not rest upon a general duty of care but must particularise the specific way in which it is said to have been breached; *Morrison's* v *Rome* 1964 SC 160 per Clyde LP at 182; *Melville Dow* v *Amec* CSIH 75, paragraphs 91, 139 and 180. The pleadings did not identify the way in which the TVT product was said to be defective. Nor do the pleadings address causation. The pursuer failed to identify the respect in which the product was unsafe, by what means the second defenders in exercise of their duty of care could have eliminated the risk and how the duty was breached.

[14] So far as lack of testing is concerned there was no attempt to offer to prove what tests should have been carried out, what the results might have been and how the defect thus manifested could have been eliminated. There was no specification of what reports of

adverse events and failure it is said that the second defenders knew about. There was an averment to the effect that "as from 2004 onwards there had been increasing reports of significant problems with the product" but the pursuer's operation took place in February 2004. Another averment (condescendence 5) to the effect that the second defenders had known of risks since at least 1988 was unsupported by further specification. It was accordingly irrelevant. The pursuer further failed to provide specification of the content of any leaflets or warnings that should have been in the press or in what respects the Instructions for Use (IFU's) were not comprehensive.

[15] On causation Mr Currie submitted that the pursuer's averments disclosed no causal connection between any negligence on the part of the second defenders resulting in a defect or risk and the injuries she says she sustained.

[16] Mr Milligan reminded me of the test of relevancy and specification set out in a number of well-known cases. These are set out in paragraphs 23 to 24 of *AH*. He submitted that the common law case was very similar to the statutory case and proceeds on the same factual hypothesis. At common law a manufacturer has a duty to ensure that its product is safe for the intended use and will not cause "further" damage to the recipient or consumer of the product. The product manufactured by the second defenders has only one surgical use, implantation. This is known to the second defenders. Further specification is not necessary (cf the brief averments in *Donoghue* v *Stevenson* 1932 SC(HL) 31 at 32). The averments in condescendence 4 were sufficient.

[17] The averments in relation to testing were matters within the knowledge of the second defenders. If they did carry out testing then they could easily aver that. In any event these averments require to be read in the context of the alleged defects which have been

clearly set out. So far as warnings are concerned I should take the same approach as I did in *AH* (at paragraph 123).

[18] On causation this had been dealt with at paragraph 119 of *AH*. Again I should take the same approach. Reference was made to *Avery* v *Hew Park School* 1949 SLT (Notes) 6.

[19] Both counsel referred me to various passages in *Richards and another* v *Pharmacia Ltd t/a Pfizer Ltd* 2018 SLT 492 (the Celebrex litigation) in support of their submissions. Mr Milligan invited me to take the same robust approach to the pleadings as did Lord Beckett in the Outer House [2017] CSOH 77 as upheld by the Inner House.

Decision

[20] In *AH* I was critical of the pursuers' pleadings (paragraph 21). These are not much better. Mr Milligan candidly accepted that the pursuer's pleadings were not of the best but contended that there was sufficient for a proof before answer. The question for me is whether or not these pleadings stumble over the line. I take the same approach to the questions of relevancy and specification as I did in *AH* (paragraph 30).

[21] At the heart of this debate is the relationship between a common law duty of care owed by a manufacturer to an end user and liability under the Consumer Protection Act 1987. While Mr Milligan accepts that at common law the onus is on the pursuer to prove her case he submits that in essence the requirements for proof are the same. Mr Currie's position is that the manufacturer is not an insurer against loss or damage; the pursuer requires to particularise the actual duty which she says has been breached.

[22] Where a manufacturer having developed, manufactured and put on the market a product which he intends should be used by an end user he has a duty to take reasonable care in the developing, manufacturing and marketing of the product not to cause injury to

the user. The fact that the product in question is one which could only be used by means of invasive surgery does not alter the duty of care but emphasises its importance. One does not need to go far to find the enunciation of that principle. In *Donoghue* v *Stevenson* Lord Atkin said this (p57);

> "If your Lordships accept the view that this pleading discloses a relevant cause of action, you will be affirming the proposition that by Scots and English law alike a manufacturer of products, which he sells in such a form as to show that he intends them to reach the ultimate consumer in the form in which they left him, with no reasonable possibility of intermediate examination, and with the knowledge that the absence of reasonable care in the preparation or putting up of the products will result in an injury to the consumer's life or property, owes a duty to the consumer to take that reasonable care."

[23] That was the approach taken by the pursuers in Richards (see paragraph 31). While there are differences in onus of proof and the defences available to defenders it is in my opinion not too far removed from the statutory case under the Consumer Protection Act 1987.

[24] Where somebody claims to have been injured by a product the investigation may focus on a number of stages in the process. There may be a defect in the design of the product. Or there may be a defect in the manufacturing process. Sometimes it may be difficult to tell which of those are at fault. For example is the use of a material which turns out to be harmful to the user a design or a manufacturing defect? An alleged failure in the marketing of a product may cover a number of scenarios. For example it may be claimed that the instructions for its use were insufficient as a result of which injury was caused. Or there was a failure to warn of known risks.

[25] Mr Currie is of course correct to say that the manufacturer of a product is not an insurer. Risks can never be totally eliminated. In the field of medical products there are always risks with medical procedures and the pursuer cannot expect that the insertion of a

vaginal mesh product is free from all risk. These are all factors which need to be taken into account in assessing the scope of the duty of care.

[26] On the other hand a person who claims to have been injured by a product will always be at a disadvantage in the litigation process. They do not have the detailed knowledge of the process of conception and design, or the research and testing that may have been undertaken. It is the manufacturer who will know all there is to know about the product. That is why when complaints of lack of specification have been made by defenders in like cases they have been dismissed by the courts (see Richards paragraphs 47 and 48). In my opinion it is not necessary to specify a "defect" as such. The first question is whether or not the product causes injury. If it does then there are a number of other hurdles which the pursuer will need to overcome if she is to bring home a case against the second defenders at common law.

[27] Mr Currie submits that his objections are not founded on lack of specification but on relevancy. However the two are closely related and I did not understand Mr Currie to suggest the second defenders did not owe a duty of care to the pursuer; merely that one had not been properly made out i.e. specified. Accordingly it is necessary to look closely at the pursuer's pleadings.

[28] In condescendence 4 the pursuer sets out something of the history of the use of synthetic mesh. I reject the submission that this is irrelevant as it does not relate to the actual product used in this case. As I understand these pleadings they relate to the use of polypropylene which the pursuer says is not a suitable substance for use in vaginal mesh products. She sets out the reasons and avers that the Manufacturer Safety Data Sheet warned against the use of mesh in permanently implanted medical devices. The averments continue that the pelvic mesh products were placed on the market with little or no clinical

data from randomised studies and that there was little evidence in relation to mid and long term safety and efficacy. She then particularises the injuries, conditions and complications suffered due to Gynecare TVT insertion with a list of such injuries.

[29] The pursuer has thus set the ground for the averments of breaches of duty of care. These are set out in article 19 as shown above. The specific duties averred relate to the "design, manufacture, marketing and supply of their products"; "that the product was safe for surgical use and would not cause further (sic) injury to patients such as the pursuer"; and "not to supply to hospitals a product they knew or ought to have known was untested for efficacy and safety". Later the pursuer avers that having become aware of adverse events and failure they failed in their duty either to withdraw the product from the market or to take reasonable steps to ensure that patients were made aware of the risks.

[30] Mr Currie submits that testing of a product such as this on a live patient is not possible. In those circumstances he submits that it is for the pursuer to set out what testing should have been carried out and what the results of such testing might have been. I reject that submission. I note that the second defender sets out in some detail the history of the development of the product including testing on prolene mesh in answer 4. The question it seems to me is whether or not these were adequate given the problems which the pursuer avers the second defender was aware of when the product was put on the market.

[31] Nor do I consider that there is merit in the submission that the pursuer required to set out what warnings should have been given in the IFU's or otherwise. A similar argument was dismissed in the *Richards* (paragraph 56).

[32] In any proof before answer the pursuer will first have to prove that the product which was implanted in her caused her injury; that the second defenders were aware or ought to have been aware (for example by testing of the product) of the risks; despite that

the second defenders put the product on the market or did so without adequate warnings; or, having later become aware of the risks failed to withdraw the product or warn of risks. That may be a difficult goal to achieve but I am not persuaded that the pursuer has not pled a relevant case.

[33] So far as causation is concerned the pursuer has set out the injuries which she says she suffered. At this stage I am not entirely clear what more is required of the pursuer. Both parties will no doubt have the pursuer medically examined and the question of causation of damage is then a matter for proof.

[34] Mr Currie also submitted that failure to properly identify the duty of care inhibited the second defenders from identifying the start date for the purposes of section 17(2) of the Prescription and Limitation (Scotland) Act 1973. It should be noted that the second defenders have a plea in law that the action is time barred which was not debated. For these reasons I do not think that I should say much at this stage. However as a matter of specification I do not consider the point has merit.

[35] Mr Currie submitted that the averments in article 5 regarding injuries, conditions and complications suffered due to Pelvic Mesh Products (see above) were irrelevant since they were inspecific and the pursuer does not aver that she had to undergo any of the treatments narrated there or that she had suffered tissue and nerve damage. He submitted that these should be deleted. I am not persuaded that I should do that. It seems to me that such averments may be relevant as part of the background and an indication of warnings that might have alerted the second defenders to risks associated with the product.

[36] The pursuer has conceded that the averment in article 5 of condescendence, "The second defenders also failed to provide adequate instructions" on page 28 of the record and the following two sentences were irrelevant and I will not allow these to go to probation.

For the reasons set out in *AH* at paragraph 145 I shall delete the averments relating to a fake report produced by Professor Carl Henegan in 2015 where these occur in condescendence 6, page 34.

[37] Subject to these matters I shall repel the second defenders' second plea in law. I reserve the question of expenses.