Neutral Citation Number: [2005] IEHC 25

THE HIGH COURT

[2002 No. 11900 P]

BETWEEN

ANNEMARIE FANNING

PLAINTIFF

AND

THE SOUTH WESTERN AREA HEALTH BOARD, FATHEL LAABEI, EUROSURGICIAL LIMITED AND RICHARD WOLF GMBH

DEFENDANTS

Judgment of Mr. Justice Gilligan delivered on the 3rd day of February, 2005.

1. The plaintiff in these proceedings on or about the 28th day of February, 2000 attended at Naas General Hospital for the purpose of having a laparoscopic cholecystectomy carried out. The second named defendant is the consultant surgeon who actually carried out the operation and as no case has been made out against him in his professional capacity it is agreed that the plaintiff's claim as against him is to be dismissed. In the course of the operation using a laparoscopic instrument known as an allis grasper, which instrument is manufactured in Germany by the fourth named defendants and distributed in Ireland by the third named defendants, one of the jaws at the end of the instrument broke off and remained embedded in the plaintiff's abdomen. Despite attempts to recover the piece of metal laproscopically the second named defendant was compelled to convert the keyhole procedure he was carrying out to an open operation and following x-ray a piece of metal was subsequently recovered from under the right side of the plaintiff's liver.

2. As s result of the open operation that had to be carried out to recover the piece of metal as embedded in the plaintiff's abdomen she suffered personal injuries, loss and damage and it is accepted by the defendants that she is entitled to succeed in her claim and her damages have been agreed in the sum of €60,000. The sole issue that arises before this court is the issue as to liability as between the three remaining defendants to the plaintiff.

3. The instrument involved is a modular forceps and scissor system which consists of three individual elements being a jaw insert, a sheath and handle. The particular instrument was sold by the third named defendants to the first named defendants in or about the month of June 1999 and had been in use for approximately eight and a half months prior to the date of the plaintiff's operation on 28th day of February, 2000.

4. In essence the first named defendants maintain that the instrument was defective as a result of which the metal jaw was caused to break off and they rely on the evidence of Professor Taylor and Dr. David Fitzpatrick that the fracture was caused by embrittlement of the metal together with the nursing evidence which is to the effect that the first named defendants cleansing and decontamination system was effective if utilised to prevent the onset of corrosion in the aluminium content of their instrumentation and further that the nursing staff who inspected this instrument on at least 30 occasions when it was used for operations saw no evidence of discolouration, tarnishing, pitting, or corrosion and in effect insofar as it is accepted by all the parties that there is evidence of corrosion in the vicinity of the jaw fracture that such corrosion occurred after 28th day of February, 2000 and was not a cause of the jaw breaking.

5. The fourth named defendant as manufacturer of the instrument denies that the metal element of the instrument was in anyway defective and maintain the case that what occurred subsequent to the sale of the instrument to the first named defendants was inadequate maintenance and care such that corrosion and pitting were allowed to develop in the instrument and it was this corrosion that caused the jaw to break off during the course of the plaintiff's operation. The remaining defendant Eurosurgicial Limited maintains that it simply is the distributor of the fourth named defendant's instruments and is its Irish agent. Mr. Kane who gave evidence on the third named defendant's behalf is the person who actually delivered the relevant instrument and he states that it is his invariable practice that the written instructions as received from the manufacturer would be delivered to the customer. The relevant documentation would be the J16 and J20 instructions but he was unable to recall precisely if on this particular occasion the documentation was furnished. Mr. Kane would not have expected this particular instrument to have failed within eight and a half months of purchase but he accepts that equipment failure does occur in respect of laparoscopic surgery and there can be a number of reasons why instruments fail. This particular instrument should have lasted for a period between two and eight years and should have been capable of being used three or four times per week.

6. In my view the only case that is made out against Eurosurgicial Limited is to the effect that the first named defendant its servants or agents should have been instructed to use demineralised water as opposed to tap water in the cleaning of the instruments and this is referred to in the document of instructions bearing the identification J20 and the third named defendants did not deliver this documentation to the first named defendants which would have enabled them to have the knowledge that demineralised water should have been used in the cleaning process.

7. I take the view that there is no substance in this allegation because it has at all times been accepted throughout the evidence in this case that the first named defendants cleaning and decontamination system is perfectly adequate if utilised to prevent corrosion developing and the essential feature is that at the conclusion of the process the instrument is properly dried and I am satisfied on the evidence that it makes no difference whether tap water or demineralised water was used in the cleaning process provided proper drying takes place In any event I was impressed by Mr. Kane and I believe he gave his evidence truthfully and bearing in mind that the first named defendants witnesses were not in a position to say that they had not actually received the relevant books of instruction I come to the conclusion that on the balance of probabilities the third named defendants did supply the first named defendants with the relevant J16 and J20 documentation. In any event for the reasons as previously set out herein by me I do not believe that whether tap water or demineralised water was used in the cleaning process is of any relevance to the issue which I have to decide in this case. However my finding brings about a situation whereby in my view no case is made out as against the third named defendant and I dismiss the claim as made against it by the plaintiff and on the notice of indemnity/ contribution as served by the first and second named defendants.

8. As regards the remaining issue between the first and fourth named defendants I take the view that the central issue is as to whether or not the fractured jaw area of the fourth named defendants instrument was sufficiently corroded on 28th February, 2000 to cause it to fracture against a background where the only other contention is that the fracture occurred as a result of embrittlement in the metal itself caused by faulty manufacture. I am satisfied on the evidence to accept the general thrust of Mr. McKenna's submission that the correct solution to the problem that arises on the evidence adduced before me is the nature of the fracture that occurred and in this regard it is clear on the evidence that if the fracture occurred as a result of embrittlement then the metal fails easily with relatively little stress applied to it resulting in a clean break and a smooth uniform fracture surface with little deformation of the metal before failure. Professor Taylor's evidence in this regard is that the appearance of the fractured surface is uniform and he stresses the importance of this fact because had the failure occurred gradually by fatigue or by stress corrosion

cracking then the surface would show two different areas one where the fatigue was occurring and the other where the final fast fracture occurred. He emphasises that if a stress corrosion crack fracture occurred the fracture area would have shown a different mode of failure. He is supported in his view by the evidence of Dr. Fitzpatrick.

9. The alternative proposition put forward by Mr. Horan and Mr. Walke is that the jaw broke of as a result of stress corrosion cracking which would not result in a smooth uniform surface on the fracture and would show two different areas of fracture.

10. As regards the issue as to whether the nursing staff saw discolouration tarnishing, pitting and/or corrosion in the jaw area of the forceps on or prior to the 28.2.2000 I take the view on the evidence adduced that the probabilities are that if corrosion had set in to such an extent as to cause the relevant jaw to fracture it is likely that there would be evidence of discolouration in the area of the fracture site and I am satisfied that appropriate inspection would require adequate training and direction and the probabilities are that on a day to day basis a degree of discolouration could easily be missed or misinterpreted and the general evidence of the nursing staff would not satisfy me on the balance of probabilities that the particular instrument was given the appropriate examination and found to be clear of any discolouration. I note and accept the evidence of Nurse Waters to the effect that if there was clear evidence of pitting or rusting the instrument would be taken out of service, that she accepts that there should be no corrosion and that if there was heavy corrosion the instrument would be taken out of circulation and this did occur from time to time. She had never previously seen discolouration or corrosion after an eight and a half month period when operating the system of cleaning, decontamination and drying as described by her. On this aspect of the evidence I am reluctant to place any significant evidential weight on the factual situation of the nursing staff having examined the forceps prior to the relevant operation and subsequent thereto in particular against a background where each of them was only relatively recently asked to cast their mind back to this particular aspect of the case and it appears that no written note or memorandum was ever made by them as to the actual condition of the forceps as of the 28th day of February, 2000. In any event, the reality of the situation is that the technical evidence as regards the nature of the fracture itself determines as to whether or not it was a fracture caused by embrittlement or a stress corrosion cracking fracture caused by corrosion.

11. For the sake of completeness I should state that I do not accept the evidence of Dr. David Fitzpatrick that there was a design weakness in the instrument along the upper surface of the linkage particularly at the transition between the main jaw body and the linkage connection element. Dr. Fitzpatrick did not satisfy me that he had adequately compared the design of this particular instrument with the norm in the industry and he was not in a position to suggest an alternative design although he accepted that it was a reasonable criticism that he could not do so. On the balance of probabilities the evidence before me demonstrates that this particular medical instrument is of a design type widely used in its own particular sphere by various competitors. I accept that the sharp corner creates a stress point but I do not accept that it is as such a design weakness. I also note that while Dr. Fitzpatrick gave evidence of a metallurgical nature he did agree with Mr. McKenna that his primary expertise was in design and not in corrosion or defective metal. I do take into account his generalised observations of support for Professor Taylor and the conclusions which he arrives at.

12. Mr. McKenna makes a number of criticisms regarding Professor Taylor's *modus operandi* of coming to his conclusion as regards the nature of the actual fracture. He takes the view that Professor Taylor's investigation into this matter was superficial, that he did not know that there were relevant standards applicable to the composition of the alloy, that he did not know whether the metal in the particular jaw conformed to the relevant standards that did not carry out an analysis of the composition of the metal, that did not carry out a hardness test on the metal itself and did not examine it under sufficient magnification. Professor Taylor clearly takes the view that these criticisms are unjustified and were not necessary for him to have had regard prior to arriving at his conclusion. I take the view that the critical matter is that of lack of magnification and I do consider that it is significant that Professor Taylor did not carry out a more extensive magnified examination of the fracture surface. He comes to his conclusion that the fracture surface was smooth and uniform and therefore a brittle fracture on the basis of a magnification of 500 times.

13. Mr. Horan's magnification photographs are to the extent of 7,000 times and Mr. Horan gives the opinion that his magnification is better than that of Professor Taylor and in this regard I accept his evidence. Mr. Horan is in a position with his magnification figures as marked 13 through to 19 to demonstrate that the fracture was a progressive one and not a single event fracture. He was able to point to very heavy corrosion in the area where the failure occurred and that there are changes in the fracture as demonstrated including micro voiding and in effect that the features of the fracture were not the same and indicate that the mechanism is a stress corrosion cracking fracture which occurred in an inter granular manner and was progressive and triggered by the corrosive process. His evidence demonstrates that the fracture surface was far from uniform and at differing points demonstrated varying characteristics over the surface range of the fracture. I prefer his evidence on this vital feature to that of Professor Taylor and Dr. Fitzpatrick.

14. I was impressed by the evidence of Mr. Malke and he satisfies me that he has the relevant qualifications and experience in relation to investigating metal failure and carrying out failure analysis. As a result of his investigation, he found on the surface of the fragments of the fracture thin brown layers. The intensity of these layers increased in the area of the fracture surface and on the fracture surface itself. He also found a lot of brown pitting on the whole surface of the fragment as demonstrated in his figures 1 and 2. On the surface of the undamaged part of the forceps he found the same type of thin brown layers and corrosion pitting. By utilising energy dispersive X-ray analysis of the layer in the pitting, he discovered elements of potassium, chlorine and oxygen and he is of the view that these findings demonstrated the dehumidified residue of a potassium chloride solution. His figures 11 to 13 show details of the surplus of the fracture which reveals an inter-crystalline fracture with areas of a corrosive attack on the grain boundaries. Chromium carbides were not established on the surface of the grain boundaries and the margin of the fracture surface and the transition of the inner surface of the mouth of the fracture are shown in his figures 13 to 15. There are heavy corrosion attacks of the material with deep cavities. The chemical compositions of the layers are similar to the one at the pitting as shown in his figure 14.

15. He comes to the conclusion that with the Scanning Election Microscope the corrosion pitting of the base material could be established on the surface of the fragments. He takes the view that the reason for this corrosion attack is an increasing concentration of a dehumidified potassium chloride solution. He takes the view that fracture mode is an inter-crystalline fracture under corrosive conditions and there is also inter-crystalline fracture propagation. He makes the point that there are no precipitations such as chromium carbides present at the grain boundaries and thus irregularities of the heat treatment could be excluded as the cause of the fracture.

16. He takes the view that the multiplicity of the corrosion pitting on the whole surface points to an insufficient cleaning of the forceps and the result of his examination in his view is that the failure of the forceps was induced by corrosion pitting which was caused by reason of an insufficient cleaning of the forceps.

17. Mr. Malke does not accept that the corrosion as shown and in particular the pitting could have happened subsequent to the 28th day of February 2000 and I accept his evidence in this regard.

18. I prefer the evidence of Mr. Malke to that of Professor Taylor and Dr. Fitzpatrick, as to the cause of the fracture in the instrument.

19. I take the view that on the balance of probabilities a degree of corrosion had set in in the vicinity of the fracture on the jaws of the instrument on the 28-2-2000 and this was the cause of the fracture at or about the stressor point. The alternative situation would be that there was no corrosion and the fracture was caused by embrittlement and while as I have made clear I do not accept this alternative theory, the reality is that other instruments used in operations in the first named defendants hospital premises had become corroded and had to be taken out of service and accordingly there is a factual basis for a failure in the first named defendants system for the care and maintenance of instruments used in operations. In my view there was a failure in relation to the care and maintenance of the modular system grasping forceps which were used in the operation on the plaintiff which led to the development of corrosion which caused the jaw to fracture during the course of the plaintiff's operation.

20. In these circumstances, I dismiss the plaintiff's claim as against the second third and fourth named defendants and I will give judgment in the plaintiff's favour as against the first named defendant in the sum of €60,000.