

BETWEEN

CHRISTINE ROSSITER

PLAINTIFF

AND

NORMA DONLON

DEFENDANT

JUDGMENT of Mr. Justice Barr delivered on the 28th day of February, 2019**I. Introduction**

1. The plaintiff is 36 years of age having been born on 12th March, 1982. She is a married lady with two children, aged 17 years and 7 years. The plaintiff has breast cancer, with metastatic disease in other parts of her body, namely her lower back, liver and brain. Her prognosis for survival in November 2018 was put at six months.

2. The defendant is a medical doctor, who at the time of the matters complained of, practiced as a GP in a two doctor practice known as the Hilltop Surgery, Raheny, Dublin.

3. In essence, the plaintiff's case is that the defendant was negligent in the care and advice which she gave to the plaintiff when she attended the defendant on 24th September, 2014. It is the plaintiff's case that in the three months prior to that visit, she had developed a lump in her left armpit, which she had discovered while in the shower. When it persisted, she became concerned and did an internet search. This revealed the possible connection between a lump in the armpit and breast cancer. The plaintiff was very concerned by this. She made an appointment to see a female GP, as she stated that she expected that a breast examination would be done.

4. It is alleged by the plaintiff that at a consultation which she had with the defendant on 24th September, 2014, the defendant performed an inadequate examination of her left axilla and did not offer to do a breast examination and, therefore, none was performed. The plaintiff alleges that the defendant simply reassured her that she could not find anything of concern following her examination of the axilla. It is alleged that the defendant was negligent in failing to carry out an adequate examination of the axilla and was further negligent in failing to offer and carry out a breast examination on that date.

5. The plaintiff further alleges that the defendant was negligent in failing to advise her to return for a review within two/six weeks, due to the fact that while the defendant could not find any lump under her arm on examination, the plaintiff was still able to feel the lump there.

6. It is alleged that in failing to do these things, the defendant acted negligently and in breach of the National Breast Cancer GP Referral Guidelines, issued by the HSE in April 2009.

7. In her defence, the defendant accepts that she saw the plaintiff on 24th September, 2014, when the plaintiff had a concern about a lump in her left armpit. The defendant candidly stated that with the exception of two things, she could not recall the details of that consultation. The two things which she did recall, were that the plaintiff said that she did not have any family history of breast cancer and that she had declined a breast examination when offered one by the defendant.

8. Other than that, the defendant had to rely on her notes, which had been made by her on the computer immediately after the plaintiff left the consultation room on 24th September, 2014. Those notes were in the following terms:-

"Concerned re? Axillary lump x 3 months

Non tender

o/e no lump palpable in axillae, declined breast exam -

no relevant FHx breast disease.

note long standing eczema o arms

imp - ? resolved LN secondary to eczema

reassure

TCI if recurs."

9. The defendant maintained that her notes represented an accurate account of what had been said and done at that consultation.

10. To summarise very briefly the events which transpired after September 2014, it is the plaintiff's case that the lump in her left armpit persisted, but due to the reassurance which she had been given by the defendant, she did nothing about it.

11. On 16th August, 2016, the plaintiff attended a Dr. Mairead Redahan at a different clinic in Raheny. She went there because she was concerned about a lump on her breast, which she had noticed approximately three weeks previously. Dr. Redahan examined her breasts and found hardness in the left breast and inversion of the nipple. She did an axillary examination, which was negative. In view of her findings, she made an urgent referral to the Breast Clinic.

12. In the following weeks, scans revealed a tumour measuring 5cm in the plaintiff's left breast. An ultrasound scan of the left axilla revealed mild cortical thickening. Due to this finding, a biopsy was carried out of the lymph node, which revealed malignancy in the node of the same type as that found in the breast. The original treatment plan was for the plaintiff to have a mastectomy and nodal

clearance, to be followed by adjuvant chemotherapy and radiotherapy for her chest. However, subsequent scans revealed that the disease had spread to other parts of her body. For that reason, the surgery was not done. Instead, the cancer was treated with a variety of chemotherapy and hormone therapy drugs.

13. Unfortunately, while there was some limited response to hormone therapy, the treatment generally has not been successful. The plaintiff's current prognosis is not good.

14. As well as the issues of negligence noted above, the court also had to consider a technical issue, which was what was the probable size of the breast tumour in 2014. For the purposes of this introduction, it is only necessary to describe the conflict between the experts on this issue in the briefest terms. The plaintiff's expert, Prof. Bundred is of the view that extrapolating back from the size of the breast tumour found in August 2016, the breast tumour probably measured 1cm/1.5cm in September 2014.

15. The defendant's expert, Prof. Price, is of the view that the breast tumour was more likely to have been in the region of 0.1cm/0.6cm in 2014.

16. The key area of difference between the experts arose due to the fact that they each came to a different conclusion as to the appropriate tumour doubling time to be adopted in this case. Prof. Bundred put that at between 100/130 days, whereas Prof. Price put it at 44/80 days. The significance of this issue lies in the fact that there was general agreement that a breast tumour of less than 1cm in size, would not be palpable on clinical examination. Thus, if the tumour in the breast was less than 1cm in size in 2014, it would probably not have been palpable on clinical examination by the GP

17. The final issue for the court was the question of quantum, which would arise if findings were made in favour of the plaintiff on the liability and technical issues.

II. Brief Chronology of Relevant Events

18. What follows is a very brief outline of some of the more relevant events in chronological order:-

2012/2014 The plaintiff attended both the Hilltop Clinic and the Centric Clinic in Raheny in relation to various longstanding complaints, including asthma, eczema and soft tissue injuries arising out of a RTA in 2008.

24/09/14 The plaintiff attended with the defendant for the consultation, the subject matter of these proceedings.

12/12/14 The plaintiff re-attended with the defendant with a complaint concerning her eczema.

Jan 2015 –

Aug 2016 The plaintiff had approximately ten visits to various doctors at both clinics in relation to various complaints. There was no complaint made in relation to her axilla.

16/08/16 The plaintiff attended with Dr. Mairead Redahan in relation to a lump on her breast. Dr. Redahan's note was admitted in evidence without formal proof. It read as follows:-

"noted lump 3/52 ago.

nipple also appeared different

mastitis 5 years ago.

no fam hx breast ca

o/e:

some inversion left nipple (new)

hardness palpable behind left nipple 12 o'clock position ? lump

no other mass/LN palpable.

plan: refer breast clinic to r/o malignancy ."

23/08/16 Plaintiff seen in Breast Clinic. On clinical examination a lump was palpable at 4 o'clock underlying the areolar complex. The plaintiff was sent for a mammogram and ultrasound scan.

23/08/16 Mammogram revealed a spiculated mass of at least 50mm with associated nipple retraction and some overlying skin thickening. Right breast was normal.

23/08/16 Ultrasound of the left axilla revealed a lymph node with mild cortical thickening. A biopsy was taken. Following biopsy, histopathological report demonstrated an, at least, grade 2 invasive ductal carcinoma with associated high grade in situ carcinoma and probably lymphovascular invasion. The tumour was greater than 90% oestrogen and progesterone receptor positive and HER 2 negative. Ultrasound guided biopsy of the axilla showed metastatic disease of similar pathology.

30/08/16 Clinical examination on surgical review showed that there was a 4cm thickening behind the left nipple with some breast ulceration.

01/09/16 Initially CT of the chest and abdomen reported no evidence of metastatic disease. However, on review, at a multidisciplinary team meeting, an addendum was produced on 06/09/16, which noted a 2cm round lymph node in the aortopulmonary window which was suspicious of metastatic disease.

08/09/16 PET scan revealed focal increased uptake in L1 and L3 bones suggesting metastatic disease.

13/09/16 Bone scan demonstrated uptake in L1, which corresponded to a focal underlying lesion on PET – CT and uptake in L3, T12 and sacroiliac joint, which could not be identified on CT. The conclusion was that there was likely suspicion of metastases in, at least, L1 and L3.

04/10/16 A bronchoscopy and endobronchial ultrasound scan was undertaken and a 1cm node in the aortopulmonary region was biopsied. Histology showed metastatic breast cancer which was HER 2 negative, weekly progesterone receptor positive and too small a sample to assess oestrogen status. A diagnosis of metastatic breast cancer was made at this stage.

III. Summary of Evidence on behalf of the Plaintiff

III.I Evidence of the Plaintiff

19. By way of background, the plaintiff stated that her usual GP at the Hilltop Surgery was Dr. O'Connor. She had attended him over the years for various complaints including mastitis, eczema and soft tissue injuries arising out of an RTA.

20. In 2014 she noticed a lump in her left armpit when she was in the shower. At first, she did not think much of it. When the lump remained for a few months, she did a Google search in relation to it and discovered that it could be linked to breast cancer. She rang the clinic and made a request to be seen by a female doctor, as she expected that there would be a breast examination.

21. On 24th September, 2014 she arrived at the clinic for her appointment with the defendant. She was called into the doctor's consultation room. She told the defendant that she had a lump under her left arm. The defendant entered this in the computer. She noted that the plaintiff was only 32 years old.

22. The plaintiff stated that she then went to the bed in the consultation room and lay down on it for an examination. She lifted her left arm up behind her head. She was not sure if she removed her top, as her armpit area may have been accessible if she was wearing light summer clothing. She was sure that she did not remove her bra. The plaintiff stated that the defendant came over to the bed and stood to her right and examined under the left armpit. On first examination, the GP was not able to find the lump. The plaintiff stated that she put her finger on the lump to indicate where it was. The GP then placed her fingers in the same area. However, she could not locate the lump. The plaintiff accepted that the defendant palpated her armpit and the surrounding area.

23. The defendant told her that she could not find any lump. She told the plaintiff not to worry. The plaintiff stated that the defendant told her that she was too young to have breast cancer and that only older women above the age of 50 would be referred for a mammogram. The plaintiff stated that she had told the defendant that the lump had been present for circa 3 months and that it was non-tender. She recalled that she had been asked about any family history of breast cancer and had replied in the negative. She did not recall any conversation about her eczema being a possible diagnosis for a transient lump under her arm. She did not recall any discussion about eczema during that consultation.

24. The plaintiff was adamant that at no stage did the defendant offer to carry out a breast examination. In cross-examination it was put to the plaintiff that the defendant would say that when she offered to carry out a breast examination of the plaintiff, the plaintiff replied "*No you are grand*" or "*It's fine*". The plaintiff stated that she did not remember being offered a breast examination at all. She was adamant that she would not have refused a breast examination if offered one, because that was the very reason why she had made an appointment to be seen by a female GP.

25. In cross-examination it was further put to the plaintiff that the defendant would say that she did examine the plaintiff's axilla and could not find any lump there. However, the defendant would say that that examination took place while the plaintiff was sitting in a chair with her left arm by her side and while the GP was supporting her bent elbow, so as to ensure that the muscles in her upper arm were totally relaxed. The plaintiff denied that that was correct. She stated that she clearly remembered lying on the bed with her arm behind her head. She stated that she was not mistaken in that recollection. It should be noted that in her evidence, the defendant said that the plaintiff had been sitting on the side of the examination bed for that examination.

26. The plaintiff denied that she was told by the defendant to return to the surgery if the lump should recur. She stated that if she had been told to return to the surgery, she would have done so. She stated that she could not recall the parting words at the end of the consultation.

27. The plaintiff accepted that her view that the defendant's examination of her axilla had been cursory and that the consultation was somewhat quick, was only a view that she came to hold after she had received her diagnosis in 2016. Prior to that, she had not had any particular complaint about the consultation. Indeed, she had returned to the surgery and had been seen by the defendant in December 2014, July 2015 and July 2016 in relation to other matters. The plaintiff stated that up until she received her diagnosis in 2016, she had been relieved that the lump in her axilla was nothing to be concerned about, as she had been so assured by the defendant at the consultation on 24th September, 2014.

28. The plaintiff accepted that her visit to Dr. Redahan in August 2016 was in relation to a lump which she had noted in her breast approximately three weeks earlier. Her nipple also appeared different. It was in relation to those matters that she had consulted the doctor. She did not think that she told Dr. Redahan about the lump in her axilla. She could not recall if she mentioned it. She accepted that she may not have done so. She accepted that it was in Dr. Redahan's notes that she had not found any lump in the axilla at that consultation.

29. It was put to the plaintiff that there was no record in the diary at the surgery that she had made any appointment prior to her arrival at the surgery that afternoon. It was put to her that she had been a "*walk-in*" patient, who had merely turned up at the surgery on spec. The plaintiff stated that she definitely made an appointment specifically to see a female GP and had been given a specific appointment time.

30. The plaintiff stated that she told the doctor that she was concerned about a lump in her armpit. She also mentioned that she was concerned about breast cancer. She recalled that she was asked whether she had any family history of breast cancer.

31. It was put to the plaintiff that the defendant would state that there was no discussion about her age as that was on the screen on the computer which was before the doctor. The plaintiff stated that she recalled the defendant mentioning her age a number of

times and saying that mammograms were usually for people in their 50s.

32. It was put to the plaintiff that having googled the significance of a lump in the axilla and having regard to her evidence that she had gone in expecting a breast examination by a female GP, and that when none was done, she must have been disappointed and possibly even dissatisfied. The plaintiff stated that when the GP told her that she was fine, she accepted that, and left it at that. She accepted that her view that the consultation had been cursory and that the GP had been dismissive of her complaint, was a view that she only came to hold later after her diagnosis in 2016. She had started to think back about the consultation in 2014 after she had been diagnosed with cancer in 2016.

33. She stated that she did not consider legal action until 2018, as she was caught up in her diagnosis of cancer and the treatment thereof in 2016 and 2017.

III. II Evidence of Dr. Andrew Burton

34. Dr. Burton qualified as a GP in 1980. He has worked as a GP since then. He joined his current practice in 1986. He is a senior partner in a six doctor practice, with 10,200 patients. He has acted as an expert witness in a large number of cases. He has done 40/50 cases for the GMC in the UK on appropriate standards in general practice.

35. He thought that the defendant's note was an acceptable note, but was not a detailed note. The entry "*concerned re-? Axillary lump x 3M*" could be very serious. The Irish guidelines indicate that an axillary lump warrants urgent referral. A duration of three months was significant, as it could indicate malignancy. Being described as "*non-tender*", would lean against infection and could lean towards it being malignant. It would increase the suspicion of possible malignancy.

36. The reference to "*axillae*" indicated both were examined.

37. The note, "*declined breast exam – no relevant family history of breast disease*," suggests a breast examination was offered, if not recommended. He would expect such examination to have been recommended. It was put to the witness that the defendant would say, that she told the plaintiff that she wanted to carry out a breast examination, he stated that that would be appropriate in the circumstances. It was put to him that it was declined according to the note. The witness stated that some women would decline a breast examination if they were with a male GP. Usually ladies would make an appointment with a lady GP for such an examination. It would be highly unusual for a patient to refuse a breast examination when seeing a female GP.

38. Dr. Burton said that the defendant's reference to eczema in her note was a reasonable observation, if it was agreed between the doctor and patient that there was no lump present in the axilla. However, there was disagreement between the plaintiff and the doctor on this. The plaintiff says that she could still feel the lump. In these circumstances, most GP's would either make a referral at that point, or tell the patient to come back in 4/6 weeks. At that stage, it would be necessary to do a further examination of the axilla to find the lump and a breast examination should also be recommended. If the patient still maintained that the lump was present, but not found by the GP, he would expect most GPs to refer the patient on.

39. Dr. Burton noted that when the plaintiff was seen on 20th August, 2014, in relation to eczema, Dr. O'Connor did not think that the eczema was infected at that stage. That note would have been before the defendant when she saw the plaintiff in September 2014. That note combined with the complaint that the lump had been there for three months, would indicate that if there had been infection, it was of less than three months duration. He also noted that when the plaintiff saw Dr. O'Connor in February 2014, there was no reference to infection of her eczema, months before she saw the defendant. That information was available to the defendant.

40. The defendant's note indicated that she thought that the lump could have been due to an infectious flare-up in the past. However the plaintiff's records did not disclose any such flare-up. Even if there was no documented flare-up, that could still be a possibility. If the plaintiff had had a flare-up of eczema, her lymph-node could also flare-up. It would usually decrease once the infection passed, but it could remain. The prior GP notes did not indicate any infection of eczema, in particular the previous note by Dr. O'Connor and the fact that he did not prescribe any antibiotic.

41. "*TCI if recurs*", that would be appropriate if the doctor and patient agreed that the lump had resolved. However that was unlikely, as the plaintiff would probably not have attended if the lump had disappeared. If the patient thought that the lump was still there, then it was not appropriate to note "*if recurs*", because the patient thought that it was there all along, so there was no question of it recurring. If the plaintiff had accepted that the lump was not there on the occasion of her visit to the GP, then the defendant's approach was reasonable. If the patient remained of the view that the lump was present, the doctor should either make a referral, or schedule a review appointment.

42. Dr. Burton stated that the National Breast Cancer GP Referral Guidelines, provided that if there was a discrete breast or axillary lump found on examination, this warranted an urgent referral (see Page 1). On Page 2, it provided that if there was a history of a breast lump, but none was found on examination by the GP, they should "*Reassure ?Reassess*". If the patient accepts that there was no lump present at the time of the examination, it would be reasonable not to reassess. If the patient remained of the view that the lump was present, then one would reassess. Is it a routine thing to reassess when one is not sure what is there. The plaintiff should have been reassessed in this case.

43. Dr. Burton gave his opinion in the following terms: based on the plaintiff's evidence, if that was accepted by the court, the GP did not carry out an adequate examination of the axilla.

44. He noted that an examination of the breast was recommended practice. No breast examination had been performed. The plaintiff had stated that she wanted a breast examination. The defendant's note indicated that the plaintiff declined a breast examination.

45. In relation to the GP's duty to give adequate advice about further assessment, if both patient and doctor agreed that the lump had resolved at the time of the examination, then it would be reasonable following adequate examination to recommend a further assessment if the lump recurred. If the court accepts the plaintiff's evidence that she thought she had a lump and the GP could not find it, most GPs would have erred on the side of caution and referred the patient on. Alternatively an acceptable alternative would have been to have recommended a further examination in 2 to 4 weeks. If at that time the situation remained unchanged and the plaintiff continued to think that there was a lump present and the defendant did not share that opinion, then in Dr. Burton's opinion most GPs would have referred the patient on for further examination. This might have been done on a non-urgent basis. The plaintiff does not indicate that any advice was given other than reassurance that she did not have breast cancer. The Irish GP guidelines contained an algorithm for breast lumps and when no lump was found on examination, it states "*Reassure ?Reassess*".

46. On 12th December, 2014, the plaintiff saw the defendant in relation to her eczema. If the plaintiff felt that the lump had not

resolved in September, there should have been a review and this was the ideal opportunity to do that.

47. Dr. Burton summarised his conclusions as follows: (1) on the plaintiff's account there was no adequate examination of the axilla, (2) a breast examination should have been done, and (3) if it was agreed between them that the lump had gone, then adequate advice was given to come back to the surgery if it recurred. However, if the patient still thought that the lump was present, then she should have been reassessed some weeks later and then referred if the status quo remained.

48. In his second report, Dr. Burton stated that if there was a disagreement as to the presence of the axilla lump, the doctor should reassess and then refer. If it was thought that the lump was secondary to eczema, the doctor should treat it, but the records show that there was no eczema infection in September 2014. If the patient continued to complain of a lump being present, then do a referral.

49. The witness was asked, if it was accepted by the court that the GP had asked the plaintiff could she examine her breast, to which she replied "There is no need to", should the GP have referred the plaintiff for a breast examination, or recommended that she should re-attend the surgery in 2 – 4 weeks, if the problem was still there?

50. In Dr. Burton's opinion, neither course would have been reasonable. The Irish guidelines contained an algorithm for breast (and axillary) lumps, and when no lump was felt on examination, it stated "*Reassure ?Reassess*". It could be argued that reassessment was not mandatory. In his opinion in order not to refer a patient, who was convinced that an axillary lump was present, the following conditions would have to be met: first, no lump being felt during adequate examination of both axillae, paying particular attention to the site the patient was complaining of, including asking the patient to describe the lump and indicate the site of the lump as far as possible. The patient is asked to palpate the lump and the examiner then replaces the patient's hand with their own. This exercise is often reversed if the examiner has felt a lump the patient is not aware of. The other axilla is used for comparison. Second, there should be a recommendation of examination of the breasts. Third, there should be reassessment after 2 – 4 weeks with no abnormality detected.

51. However in this scenario with the patient still considering that the lump was present, following reassurance from the doctor, in his opinion most GPs would have made a referral.

52. Dr. Burton stated that if he found a lump in the axilla, he would recommend a breast examination. If the doctor found a lump in the breast, that would support the presence of an axilla lump, so the GP should go back and examine the axilla again and should make a referral.

53. In relation to the defendant's expert's report, his opinion was based on the contemporaneous note made by the defendant. Dr. Burton did not accept that it was a detailed note by the GP. He noted that Dr. Boland based his opinion on the defendant's account that the plaintiff had refused a breast examination. He did not take account of the plaintiff's version of events, to the effect that she was not offered a breast examination.

54. He did not think it unusual that the plaintiff did not complain about the defendant's examination of her in September 2014, due to the fact that she had left the surgery happy and reassured that she had no cause for concern. In such circumstances she was unlikely to mention the visit again. He was of opinion that a competent GP would find a lump on the breast if it measured 1cm or greater.

55. In cross-examination, Dr. Burton said that a GP's note was primarily drawn up as an aide memoir to assist the doctor and it could also have a role in any subsequent litigation. It was good practice to make the note either during or immediately after the consultation. Usually things contained in the note, would be matters that were raised or discussed with the patient during the consultation, unless there was a specific afterthought that occurred to the doctor later on. In general terms, he found the defendant's note satisfactory.

56. The previous note of 20th August, 2014 indicated that the eczema was not infected. It had become infected when the plaintiff re-attended with her GP in December 2014, at which time antibiotics were prescribed. He accepted that if the lump had disappeared, eczema was a possible cause.

57. He accepted that the plaintiff did not appear to hold the view that her consultation with the defendant in September 2014 had been dismissive. She only came to hold that view after her diagnosis in 2016.

58. It was put to the witness that when the doctor in 2016 could not find any axillary lump, this would suggest that the lump was not palpable in 2014. Dr. Burton accepted that it was plausible that the lump may not have been palpable in 2014, or the doctor in 2016, Dr. Redahan, may have been concentrating on the breast lump which had been discovered at that examination. It was put to the witness that usually a malignant lump would get bigger over time. If it could not be found on examination in 2016, it was plausible that it was not palpable in 2014. Dr. Burton stated that that was not his area, but he agreed that the finding of Dr. Redahan of there being no axilla lump in 2016 was surprising if it was a malignant lump, which had been in existence in 2014.

59. He accepted that the defendant had asked about family history of breast cancer. He also accepted that the term "axillae" was in the plural. He accepted that 12 minutes would be a reasonable time for a consultation. He also accepted that if a patient declines to have a breast examination, it would be inappropriate for a doctor to perform one.

60. It was put to the witness that the defendant said to the plaintiff "I would like to do a breast examination" and that that was a normal and acceptable means of putting the proposition. Dr. Burton accepted that those words would be reasonable for the defendant to use in the circumstances.

61. Dr. Burton accepted that the proper method of examining the axilla was to do so when the patient is sitting in a chair, with the arm muscles relaxed. The patient's arm would not be behind her head. It was put to him that the defendant would say that she held the plaintiff's elbow, so as to ensure that her arm muscles were relaxed. Dr. Burton stated that that was the correct method for carrying out such an examination.

62. It was put to the witness that the defendant's note stated "*reassure*", which the defendant would say meant that she reassured the plaintiff that eczema was a possible explanation for an inflamed lymph-node. Dr. Burton agreed that it was a possible explanation.

63. It was put to the witness that if the doctor could not find the lump and the patient could not find it, it was reasonable to suggest that she should return if the lump recurred. Dr. Burton stated that that was appropriate if the patient agreed that the lump was not

present.

64. In relation to the guidelines, it was put to the witness that while an axilla lump was specifically referred to on Page 1, the reference to "*breast lumps*" on Page 2 only referred to breast lumps and did not refer to axilla lumps. Dr. Burton accepted that on Page 2 it only referred to a breast lump, but the sight of the lump did not matter. If there was a complaint of an axillary lump, but it was not found, the appropriate course would be "*Reassure ?Reassess*". He accepted that the algorithm referred to breast lumps, but he thought that it also included axillary lumps. In his opinion the same treatment protocol applied to a suspected axillary lump. However, he accepted that an axillary lump was a lower level of concern than a breast lump in terms of breast cancer.

65. It was put to the witness that the recording on ultrasound carried out on 23rd August, 2016 in relation to the lymph-node of "*mild cortical thickening*" meant that the lump in the lymph-node would not have been palpable. Dr. Burton stated that the technician carrying out the ultrasound commented on the lymph-node because he or she thought that there was something there. It was put to the witness that the note made by Mr. Alan "*axilla oe N*" meant that the axilla examination was negative. He stated that that was a clinical finding made by the surgeon.

66. It was put to him that the CT scan of 30th August, 2016 showed bilateral axillary lymph nodes less than 1cm, whose appearances were deemed not to be concerning. He accepted that those nodes were less than 1cm. Counsel suggested that if the plaintiff had cancer in the axilla, there was no reason that it would reduce over time. Dr. Burton stated that that question would have to be put to an appropriate expert. He would expect a lump of 1cm to be palpable, if it was located near the surface.

67. He was of opinion that a 1cm tumour in the breast, would be palpable by a GP. That was a rule of thumb. The lump may not be well-defined, in which case it may not be palpable. He accepted that a GP could discount a small lump less than 1cm.

68. He accepted that if the plaintiff had had a lump and it was then gone, this could indicate a recovered eczema infection as a plausible explanation for the lump. He would agree with the opinion of Dr. Boland that the guidelines had been adhered to, if the GP's note is accepted as being correct.

69. In re-examination, Dr. Burton stated that the biopsy results indicated that the lymph-node in the axilla was similar to the cancer in the left breast. It was connected to the tumour found in the left breast.

70. He agreed that the question put at, Day 1, Page 111, Question 457, suggested that the defendant had no recollection of the plaintiff agreeing that there was no lump present.

71. Dr. Burton agreed that it would be very unusual and very unlikely that a patient would attend a GP with a concern in relation to breast cancer and yet refuse to have her breasts examined by a female GP.

III.III Evidence of Professor Nigel Bundred

72. Prof. Nigel Bundred was called as a witness for the plaintiff. He is a professor of surgical oncology and a consultant surgeon at the University Hospital of South Manchester NHS Foundation Trust. He qualified as a doctor in University of Newcastle-upon-Tyne in 1980. He has fellowships in the Royal College of Surgeons of Edinburgh, Glasgow and England.

73. In relation to tumour grade, Prof. Bundred stated that there are three grades of tumour. Grade 1 is the slower growing tumour. Grade 2 is faster growing and Grade 3 is more aggressive than the other two grades. When grading a tumour the histopathologist will look at the characteristics of the cells taken from the biopsy. Firstly, they will look at tubule formation, this is to ascertain whether there are holes in the cells. An aggressive tumour will not have tubules and this will tend to put them into Grade 3. Slower cancers tend to have a number of tubules in the cell. Secondly, the histopathologist will look at pleomorphism, this looks at the size of the nucleus and the shape and size of the cells themselves. They will be given a score on this analysis. Thirdly, the histopathologist will look at the mitotic count, this measures how many mitotic features the pathologist can count in 10 fields under the microscope. It is effectively a measure of the proliferation rate of the cancer. This is a key determinant in how fast the tumour is growing. If there are less than seven visible mitotic figures on the microscope this would get a score of one, which would mean that the tumour was slow-growing. If it was more than 20, it would get a score of M3, which is fast-growing. In order to grade the cancer you add the scores under these three headings on a scale of 1 to 3 each. The lowest score available would be a combined score of three. Anything from 3 to 5 is Grade 1. A score of 6 to 7 is Grade 2 and a score of 8 to 9 is Grade 3.

74. The plaintiff's overall score was 3+3+1 giving a total of 7, which put the plaintiff at Grade 2. Both the plaintiff's experts and the defendant's experts agreed that the plaintiff had a score of M1 and an overall grade of 2.

75. Prof. Bundred was of the opinion that a diagnosis of breast cancer could have been made in 2014 if the plaintiff had been referred to a breast clinic. If diagnosed then, she would have required a mastectomy and an axillary clearance. She would also have needed adjuvant chemotherapy and possibly radiotherapy for her chest. That treatment would probably have cured her cancer.

76. In 2016 the plaintiff was found to have a 5cm lump in her breast, which was oestrogen and progesterone receptor positive, HER-2 negative, and Grade 2. The interval between presentation in September 2014 and diagnosis in August 2016 was 693 days. The imaging report from 2016 showed a 50mm lump and nipple retraction.

77. In explaining tumour doubling time, Prof. Bundred said that it was necessary to work back from the 5cm tumour discovered in 2016. A large number of studies had been undertaken over the years in relation to the growth rate of various tumours. It was found that when they had started breast screening initially, the signs were not picked up until later. By comparing the previous scan and the later scan it was possible to do a calculation of the time that it took for the tumour to double in size. That analysis was done by comparing a number of scans in chronological order. Tumour doubling time can vary from person to person depending on their family history, the grade of the tumour (Grade 2 being slower than Grade 3), and the age of the patient. For example Tilanus-Linthorst found a faster rate of growth in younger patients, who had a family history of breast cancer. Prof. Bundred had set out his method of calculating the tumour doubling time at page 35 of his first report.

78. In his first report, Prof. Bundred indicated that it was his view, that in women who are younger there was an increased speed of tumour doubling and for that reason he thought that 80 days was the correct doubling time for the plaintiff. Conventionally, they calculated the doubling time in premenopausal women based on Peer *et al.*, which has a mean doubling time of 80 days (range 44 – 147 days). If they used a doubling time of 80 days, then the tumour which was 5cm at diagnosis, would have been around 0.8cm in size in 2014. The tumour would have been diagnosable because of the surrounding ductal carcinoma in situ at that time. It would also have been detected because of the axillary nodes which were involved.

79. Prof. Bundred stated that on reflection, he came to the view that his estimate of the tumour doubling time was incorrect. The tumour doubling time of 80 days given in the Peer *et al.* paper was not accurate in this case. That paper had been written in 1993. Of a total of circa 107 patients, only 32 were less than 50 years old. In 1993 50% of women less than 50 years, would have had Grade 3 tumours. In this case, the plaintiff had a Grade 2 tumour and her mitotic count was M1. So while in general it could be said that younger patients tend to have faster growing tumours, in this case the plaintiff was shown to have a slower growing tumour. For that reason it was not appropriate to take a tumour doubling time of 44 – 80 days.

80. Prof. Bundred stated that in giving his opinion in his first report, he had missed the significance of the histopathology report given by Dr. Staunton. In particular, he had not taken sufficient account of the specific factors concerning the plaintiff's tumour and in particular the following: no family history of breast cancer, a Grade 2 tumour, an M1 score, and the fact that despite the fact that she had not responded well to therapy, she had exceeded the normal survival time from diagnosis of 24 months. All of this supported the conclusion that this was a slower growing tumour. For that reason, he had revised his opinion in relation to the tumour doubling time to somewhere between 100 days and 130 days. Using that calculation of the tumour doubling time, and applying that to a lump measuring 5cm in 2016, this would mean that there was a lump of approximately 1cm – 1.5cm in the breast in 2014.

81. The generally accepted threshold for a palpable tumour, was that anything of the size of 1cm or greater, should be palpable on examination by a doctor. Indeed, Prof. Bundred stated that it was possible that even a smaller mass may be detectable on palpation, depending on the position of the tumour.

82. Prof. Bundred stated that he based his analysis on the paper by Michaelson published in 2003. It summarised all the available data at that time. It was a very large study, based on 810 patients. The various estimates were set out in Table 3. The authors estimated a median doubling time of 130 days. Prof. Bundred felt that this paper was superior to the other papers as it was based on a larger number of patients.

83. Prof. Bundred stated that he had given a range of tumour doubling times calculated at 80 days, 100 days and 130 days. Given the factors applicable to this specific patient, he was of the view that the tumour doubling time in her case would be nearer the 130 day mark. If that was adopted, that would mean that the tumour was approximately 1.5cm in 2014. Even if 100 days was taken as the tumour doubling time, that would give a tumour of 1cm in 2014. These would both be easily detectable. A mammogram can detect a tumour down to 5mm.

84. The ultrasound of the left axilla in 2016 revealed "mild cortical thickening". Any cortical thickening greater than 3mm, was indicative of a possibly malignant growth and therefore a biopsy was needed. Here the thickening was measured at 3.7mm, so a biopsy was done. The histopathology report of 23 August 2016 indicated that the lymph node in the left axilla had metastatic carcinoma similar to the left breast.

85. Prof. Bundred was asked if the plaintiff had told her GP in 2014 that there was a lump in her left axilla, which had been present for three months and if it was accepted that the lump remained from that time until 2016, what was his opinion as to how long the cancer had been in the lymph node. Prof. Bundred stated that he took the tumour doubling time at 130 days, it was clearly possible that the cancer was in the lymph nodes all along. It was also possible that the cancer had rested in the lymph nodes for a period. He thought it highly probable that there was cancer in the lymph nodes in 2014.

86. In relation to the likelihood of distant metastases in 2014, Prof Bundred pointed out that Norton *et al.* had indicated that nodes and metastases in distant organs occur by multiple tumour emboli, through the lymphatics and the bloodstream. The earlier a patient is diagnosed and the longer the delay between the presentation with the tumour and the subsequent diagnosis, the greater the chance that emboli will have left the primary tumour site and spread to the nodes and then distantly. The plaintiff had a 693 day delay (almost 2 years) and in that time the tumour had spread and grown in the breast. Richards *et al.* found delays longer than six months were associated with nodal metastases and a poorer survival from breast cancer.

87. He did not think that the plaintiff had distant metastases in 2014. That would mean that it was outside the regional lymph nodes, at which time a patient would have had a survival rate of 24 months. He thought that in 2014 this plaintiff had tumours in her breast and in her axilla only. These would have been treatable by surgery and other treatments. The Richards *et al.* paper had looked at 87 studies and found that the delay of 3 – 6 months was associated with a lesser survival rate.

88. Prof. Bundred was of the view that had the plaintiff been diagnosed in 2014, she would have had a survival rate of approximately 47 years. He remained of that view. The time period may shorten slightly if the tumour was held to have been 1.5cm in 2014.

89. He pointed out that in his report he had set out an actuarial survival table into which one would put the patient's age, the size and the number of nodes and it would give the number of people who would die based on an actuarial calculation. For a healthy person of the plaintiff's age, the figure of 49 years, would be shortened by 8.8 years. If the plaintiff had had treatment in 2014, the survival rate would improve by 6.1 years, which would mean that her shortening of lifespan would be 8.8 years less 6.1 years giving a 2.7 years reduction, meaning that she would have had a generally expected survival period of 47 years. If the tumour diameter was in the region of 1cm/1.5cm it might reduce life expectancy to 47 or 45 years.

90. In cross-examination Prof. Bundred accepted that he was not an expert in GP care, so he could not comment on that aspect. Nor could he comment on the conflict of evidence between the plaintiff and the defendant in relation to what actually happened at the consultation. If a patient was complaining of an axillary lump, that was a symptom of breast cancer. They may not have any other symptoms, but one would not usually have other symptoms in breast cancer at that stage.

91. The scan done in 2016 revealed a "*moderately differentiated cancer*", which just meant that it was a Grade 2 cancer. It was oestrogen receptor and progesterone receptor positive, suggesting that the tumour was hormone sensitive. The diagnosis was made after the biopsy. When assessing the size of the tumour in 2016, you take the mammographic size of a tumour, which was 5cm, not the clinical size.

92. He accepted that the GP in 2016 did not find any axillary node. A cancer containing lymph node would feel different from an ordinary lymph node, in that it would be hard, not spongy. He accepted that Dr. Redahan had recorded that she could not feel any lymph node in 2016.

93. It was put to Prof. Bundred that if the node had been cancerous in 2014, one would expect it to be enlarged and to be palpable in 2016. He stated that that would not always be the case, because the cancer can spread to other nodes. It may not always grow in the initial node, perhaps not by any significant amount, if the tumour was slow-growing.

94. Prof. Bundred said that the defendant's expert, Prof. Price, had not said what precise tumour doubling time she had used to calculate the size of the tumour in 2014. He estimated that she had used a tumour doubling time of 40 – 75 days which was lower than 80 days. He accepted that Prof. Price and he had used the same methodology for measuring tumour doubling time.

95. It was put to the witness that Prof. Price would say that a tumour in the breast of the size of 1cm, would not be palpable. The witness stated that it would depend on where the lump was. If it was close to, or behind the areola it could be detected on palpation. He accepted that the literature stated that a GP should be able to palpate the lump at 1cm or greater, but on occasion it would be palpable at a lower size. He accepted that 1cm was the normal threshold.

96. He disagreed with Prof. Price in relation to the presence of metastatic disease in 2014. He was of the view that the plaintiff developed that later, when she had distant metastases.

97. It was put to the Prof. Bundred that eczema could account for the node varying in size. He disagreed, stating that a node with cancer would feel very different. It is hard in texture. It was put to the witness that the plaintiff had been with her GP previously in relation to eczema infection and had returned to the GP in December 2014, so her eczema was active. Witness stated that usually treatment would deal with any intermittent infections.

98. The witness was asked about the finding on the ultrasound scan of "*mild cortical thickening*" in the left axilla. He stated that this was a way of making a diagnosis on the basis of the ultrasound scan. If there was thickening greater than 3mm then a biopsy was indicated. That had been done in this case and it confirmed a tumour.

99. The witness was questioned extensively in relation to his change of opinion in relation to the tumour doubling time and the probable size of the tumour in 2014 as given in his first report and the comments in his letter dated 9th January, 2019 and his change of opinion as set out in his second report dated 16th January, 2019. It was put to him that in his first report he had estimated that the tumour doubling time of 80 days was the correct doubling time for the plaintiff. Given a lump measuring 5cm in 2016, this meant that the plaintiff probably had a lump measuring 0.8cm in 2014.

100. It was further put to him that in his letter dated 9th January, 2019, he had stated that he calculated that the tumour would have originally been 0.8cm, which was "*little different*" to Prof. Price's calculation of 0.6cm. However, in his second report dated 16 January 2019, he had opted for a tumour doubling time of 130 days, meaning that the breast tumour would have been 1.5cm in 2014.

101. Prof. Bundred explained that his change of view had come about because when he saw Prof. Price's report, he saw that she had taken a tumour doubling time of less than 80 days. He had gone back and rechecked the medical records. He said he had missed the significance of the histopathology report from Dr. Staunton, which had given an overall score of seven, being a Grade 2 cancer, but more importantly had given a score of M1. He felt that these factors were highly significant when calculating the likely tumour doubling time in relation to this plaintiff. He accepted that he had missed the significance of the M1 score when initially giving his opinion.

102. He felt that having regard to the following factors: no family history of breast cancer, a Grade 2 cancer, the M1 score and the fact that although she had not responded to therapy, the plaintiff had exceeded the 24 month expected survival, all of this indicated that in the plaintiff's case, she had a slow growing tumour.

103. In those circumstances based on the paper by Michaelson *et al.*, it was appropriate to go for the median figure given in that study in table 3, where a median doubling time of 130 days was given. If that tumour doubling time was adopted, this would mean that the tumour measured 1.5cm in 2014.

104. He had also given a range of possible doubling times, ranging from 80 days (0.8cm), 100 days (1cm), and 130 days (1.5cm). He felt that given the combination of factors outlined above, it was more appropriate to opt for the estimate of 130 days, rather than any lower estimate. For that reason it was his opinion that the breast lump measured circa 1.5cm in 2014.

105. He felt that it was appropriate to go on the Michaelson *et al.* paper, because it was by far the largest study, having looked at 810 patients. He did not think that it was appropriate to look at the Tilanus-Linthorst paper, as the plaintiff had no relevant family history of breast cancer. The witness accepted that in his first report he had estimated the size of the lump in 2014 to have been 0.8cm, but when he factored in the significance of the M1 score, this caused him to come to a different conclusion, that the size of the lump was between 1cm/1.5cm.

106. It was put to the witness that the age of the patient was a significant factor, in that in this case the plaintiff was a young woman of 32 years of age in 2014. Prof. Bundred stated that while age was a significant factor, it was not determinative of the growth rate of the tumour. While one would take age into account, one had to have regard to the specific factors relevant to that specific patient. When one did that, age became a less relevant factor in itself. In this case, the patient specific factors outlined above, all pointed to the plaintiff's tumour being a slow-growing one.

107. Prof. Bundred stated that most patients would present with a breast lump, but 1% would present with only an axillary lump. He did not think that the fact that the lump in the breast was behind the nipple, made it more difficult to find, it was actually an easier area in which to locate the lump, because it was pushed towards the surface.

108. The oestrogen receptors promote cell growth. He accepted that 70% of breast cancers were oestrogen positive. Oestrogen negative tumours are always M3 i.e. fast-growing.

109. Prof. Bundred accepted that he was aware of the plaintiff's breast profile when doing his first report. He was also aware that the tumour had been classified as Grade 2 and he was aware of the plaintiff's age and family history.

110. It was put to the witness that Prof. Price had set out her methodology at page 37 of her report. He noted that Prof. Price stated that she assessed tumour doubling time on the basis of the evidence set out in Table 2 in the paper from Peer *et al.*. He did not feel that that was the correct table to use. Nor did he accept the data set out in the third table in the Tilanus-Linthorst paper, as that was only for people who had particular genes and had a family history of breast cancer, accordingly that was not the appropriate table to use to calculate tumour doubling time.

111. He accepted that in his first report he had quoted from the Tilanus-Linthorst paper, because it had dealt with young women, but on reflection he thought that it was not an accurate statement of the plaintiff's position because she had no family history of breast cancer.

112. He stated that it was now generally accepted that Peer *et al.* was not appropriate due to the necessity to take patient specific factors into account.

113. It was put to the witness that at page 35 of his first report, it was clear that he knew the plaintiff's age and that she had no family history of breast cancer, he had accepted the papers by Tilanus-Linthorst and Peer *et al.* and he had come to the opinion that 80 days for tumour doubling time was correct. It was put to him that he only changed that view after he had seen Prof. Price's report. Prof. Bundred stated that when he saw that report, he decided that it was necessary to take a wider view of the facts to take account of the specific factors in this case. He accepted that he had not given enough weight to the appropriate factors in his initial report. When he looked again at all the relevant factors, including the histopathology score of 3+3+1, this caused him to change his opinion of the tumour doubling time.

114. He accepted that the Tilanus-Linthorst and Peer *et al.* papers were the standard papers to use. However he had set out clearly why, in the light of the histopathology score of 3+3+1, it was appropriate to lengthen the tumour doubling time in this case. The paper by Peer *et al.* was a well-known paper, but it was somewhat old, dating from 1993. It did not give much detail about the number of patients aged 32 years, or even those under 50 years. It was put to the witness that in the Peer *et al.* paper, 80 days was the appropriate tumour doubling time for patients under 50 years, so Prof. Price was correct to take a tumour doubling time of 44-80 days. Prof. Bundred said that Peer *et al.* had nobody under 41 years. It was only a guide. That was all he was saying.

115. It was put to the witness that in the Tilanus-Linthorst paper from 2005, it found that amongst younger patients there was a shorter tumour doubling time. Prof. Bundred stated that that paper dealt with people who had a family history of breast cancer. Accordingly, it was not appropriate to be used for this plaintiff, who had no such history. On reflection, he was satisfied that the plaintiff did not fit into their paradigm. It was put to the witness that he knew the plaintiff's family history when he quoted from that paper in his first report. He accepted that that was correct, but stated that on reflection he realised that the plaintiff was not in the particular cohort of patients covered in that paper. Once he saw the M1 score, he realised that he would have to revise his estimate of the tumour doubling time. He then looked back at the absence of any family history of breast cancer and on that account came to the conclusion that the Tilanus-Linthorst paper was not relevant. It was learning of the M1 score that caused him to change his view.

116. It was put to the witness that in his first report he had estimated the size of the tumour at 0.8cm, but after he saw Prof. Price's report he changed that to 1.5cm. He was asked whether that was only due to learning the mitotic score. Prof. Bundred stated that in his first report he had given the standard tumour doubling time of 80 days. In his second report he had had regard to the M1 score and the absence of a family history, so he revised his views of the tumour doubling time and of the probable size of the tumour in 2014.

117. It was put to the witness that when he realised that the size of the tumour being less than 1cm, as per his original report, he knew that that would not have been palpable and this accounted for his change in opinion. The witness denied that that was the case. He stated that when he looked at the histopathology report initially, the 3+3+1 was somewhat of a throwaway and he did not pick up on it. He realised later that he had missed the mitotic score of one, so he went back and reviewed his opinion.

118. It was put to the witness that surely that had been a significant characteristic in determining growth rate. He stated that he only realised what it meant, when he looked at it again and in the light of that he did his second report. He accepted that he had done hundreds of cases in relation to tumour size. It was put to him that the Bloom-Richardson score was fundamental. He said no, that was only in relation to younger women, that it was important. He apologised for missing the significance of the M1 score in his first reading of the histopathology report. He accepted that he had seen that the plaintiff was 32 years old and had a Grade 2 tumour, but the specifics had been in the histopathology report, which he had missed. When he saw that, he then changed his opinion. Indeed he thought that Prof. Price had also missed that report.

119. Prof. Bundred stated that back extrapolation in relation to the size of a tumour at a previous point in time was done on a mathematical formula. Both Prof. Price and he had used the same formula. The size of the tumour in 2016 was ascertained. The size that it was in 2014, was based on what tumour doubling time you used. Prof. Price had used a tumour doubling time faster than 80 days. He thought that that was too short.

120. He stated that in his first report he had used the Michaelson *et al.* survival calculator. This involved inputting the node size, age, grade of tumour and the oestrogen and progesterone receptor status. He would go by that calculator. He thought that the Young *et al.* paper was a bit old. One can now use an actuarial calculator. It was worth noting the fact that the plaintiff had not responded to treatment and was still alive, that indicated that the tumour was not fast-growing; on that basis he had also gone for the tumour doubling time of 130 days, giving a tumour size in 2014 of 1.5cm.

121. It was put to the witness that he was of the view that the paper by Peer *et al.* was deficient in not taking account of patient specific factors and in particular her score of M1. The witness agreed and stated that one also had to take account of the fact that the tumour was Grade 2 and that M1 was the lowest possible score, which implied that the tumour was not growing very fast. It was put to him that mitotic score was only one factor. There were other factors such as the fact that she had no symptoms for two years prior to 2016, which should be taken into account. The witness stated that a lump in the lymph-node was a symptom in itself. He would not have expected any systemic symptoms at that time.

122. Prof. Bundred was questioned in relation to his letter to the plaintiff's solicitor dated 9th January, 2019. It was put to the witness that the first paragraph in the letter and its general phraseology indicated that it was a private letter between him and his instructing solicitor, which he did not think would have to be disclosed, or did not intend should be disclosed to the opposite side. Prof. Bundred stated that he was aware of the rules in Ireland on disclosure and was aware that his letter would be disclosed as part of the general disclosure process.

123. In the third paragraph of the letter he had stated that he was concerned that Prof. Price referred to "*mild cortical thickening*" in the ultrasound of the axilla node in 2016, and assessed that as being mild/minor, implying that there was probably nothing there in 2014. He did not agree with that assertion. The cortical thickening meant that there was an indication to carry out a biopsy, which was in fact done. He accepted that in the letter he had said that it was important to get a copy of the ultrasound scan of the axilla.

124. It was put to the witness that the thrust of his second report was that he changed from a tumour doubling time of 80 days giving a breast lump of 0.8cm to 130 days and a breast lump measuring 1.5cm. It was put to him that he had said that this change in opinion was based on patient specific factors and he criticised Prof. Price's reliance on the papers by Tilanus-Linthorst and Peer *et al.* He stated that Prof. Price had reached the opinion that because the GP who examined the plaintiff in 2016 could not palpate the lymph nodes in the axilla, this meant that the GP who examined the plaintiff in 2014, would also not have been able to palpate them. Prof. Bundred stated that he thought that that was a key part of the case and he had said so in his letter. For that reason he

advised obtaining a copy of the ultrasound scan. He felt it was important to look at the scan to see the extent of the cortical thickening. He said that it came to him that the M1 score and the ultrasound scan were important. He wanted to show that Prof. Price's assertion that because there was only a small node in the axilla, that did not mean that there was only a small amount of disease present.

125. He accepted that in the letter he had calculated the size of the tumour in 2014 at 0.8cm and that Prof. Price had estimated it to have been 0.6cm, which was fairly close to his estimate. He accepted that the results reached in his first report and the conclusions in Prof. Price's report were very close. He said that it was only when he reviewed the histopathology report and saw the 3+3+1 scores, that he realised that her estimate was wrong.

126. It was put to the witness that in his letter, he had said that his conclusion was "*little different*" to those reached by Prof. Price. He stated that the measurement of 0.8cm was based on a tumour doubling time of 80 days, so in order to get 0.6cm, Prof. Price must have used a faster doubling time.

127. He accepted that it was relevant that the clinicians were not able to feel the lymph node on examination in 2016. However, he thought that they may not have made a great effort in that regard, because she had presented with a large breast lump, so radiological examination was definitely warranted.

128. He was asked to comment on the note made by Dr. Allen which read "*Ax n N*". He stated that this was an extremely brief note and it was not clear at all what it meant. He thought that it was a somewhat lax note. Perhaps because of the presence of the significant breast lump, the medical team were not as concerned with the axilla nodes.

129. It was put to the witness that the CT scan had reported bilateral nodes less than 1cm, which implied that when they were not concerning. He stated that the CT scan was less accurate in determining size. They knew that the axilla node was concerning, because that had been shown up on the ultrasound scan and a biopsy had been done in light of that scan. A CT scan was not the correct way to assess the size of the lymph-node.

130. Prof. Bundred was asked about the articles cited in his second report. In the Peer *et al.* paper, in Table 4 there was an analysis given of the literature on tumour doubling times. Tabanne gave a mean doubling time of 115, days with a mean age of 48 years. So the Peer *et al.* paper recognised that there was a difference in conclusions in different literature.

131. It was put to the witness that he had opted for Michaelson *et al.* which gave a tumour doubling time of 130 days whereas other papers had given different times. Prof. Bundred pointed out that Arnelove dealt with tumours of Grade 1, 2 and 3 in Table 4. There was a small number of samples for Grade 2, which showed a slower growth rate. The age range was 42 to 87 years in that paper.

132. It was put to the witness that age was a huge factor in relation to tumour growth and here the plaintiff was young at 32 years. Prof. Bundred stated that in assessing tumour doubling time you have to look at all the factors, such as whether the tumour was grade 1, 2 or 3 and not just at the age of the patient. Here the plaintiff was Grade 2 and she was M1, which implied a slow-growing tumour and on that basis he had taken a longer doubling time. He put her in the range of 130 days. Once you had a low grade of tumour and a low M1 score, age was not that relevant. It was the specific factors applying to this specific patient, that were the relevant factors.

133. It was put to the witness that in his first report he had estimated the tumour doubling time based on the Tilanus-Linthorst paper. The witness accepted that those people were not BRCA 1 or BRCA 2, but they had a family history of breast cancer. Their median doubling time was 83 days. However that was not relevant here, as the plaintiff did not have a positive family history for breast cancer.

134. It was put to the witness that he had stated that in younger women he thought that a tumour doubling time of 80 days was correct and that that was correct for the plaintiff, at a time when he knew that she was a young person and did not have a family history of breast cancer. He repeated that when he saw the M1 score, that was something that was specific to the plaintiff and accordingly he re-evaluated the doubling time from 80 days to 130 days.

135. It was put to the witness that in the Tilanus-Linthorst paper age and risk group were relevant. While they had acknowledge the limitations in getting data, he had been happy to quote that report and to use their estimate of a tumour doubling time of 80 days. The witness accepted that he had known that the plaintiff did not have a family history when he tried to estimate the tumour doubling time. When he saw the M1 score he saw that she would not conform to the analysis in the Tilanus-Linthorst paper. Age was not that relevant. It all depended on the type of tumour and the rate of growing, being the M1 score. He got a better guide once he knew that she was a Grade 2 and M1 score.

136. In relation to the Michaelson paper, Prof. Bundred stated that this was the largest study covering 810 patients from 2003. It contained mathematical calculations for tumour doubling time and gave a doubling time of 130 days. This plaintiff had a Grade 2 tumour which was M1. The Peer *et al.* paper only had 26 young patients, which was a very small cohort. That the plaintiff had an M1 score was agreed by both experts, as was the fact that the tumour was Grade 2. These were the most important factors in this case.

137. It was put to the witness that he had not even referred to the mitotic score in his first report. He said that it had been highlighted in his second report. Prof. Price did not agree that that score was very important so as to displace age as a relevant factor. The witness stated that Prof. Price had not even commented on the grade of the tumour in her first report. That was an important factor and it showed that they had both missed things in their first reports. It was put to him that Prof. Price would say that the mitotic score would not displace age to the extent that he argued. He stated that most clinicians would say that if a tumour was Grade 2 and had an M1 score, they were the most significant factors, because they were tumour specific factors for that particular patient. In those circumstances age per se was irrelevant.

138. Prof. Bundred accepted that Michaelson *et al.* had not focused on grade as a specific factor. It was a very large study which gave a general range. If one took 80 days as the median, where a person had a Grade 2 tumour and an M1 score, they would come in above 80 days, somewhere between 100 days and 130 days. It was put to the witness that the authors did not support his view that age was not relevant in face of specific factors. He stated that the key factors were the grade of tumour and how fast it was proliferating. Clinicians would individualise the treatment depending on the rate of growth of the tumour. In addition, in this case the plaintiff had exceeded the survival rate of 24 months. That indicated that the tumour must be slow-growing.

139. In relation to Prof. Price's report at page 22, she merely said that as a younger woman she would use a tumour doubling time of

less than 80 days. She did not say why she adopted that tumour doubling time. She did not factor in that the tumour was a Grade 2 tumour, which is slower growing. He reiterated that he did not think that 80 days was appropriate, where a person had a Grade 2 tumour and an M1 score. These were specific factors relevant to the patient.

140. Kuroishi did not deal with grade, but dealt with age. In Table 4 it was stated that for patients less than 39 years, the plaintiff was in the 31% who were found not to be not fast-growing, that paper showed that it did not depend on age, it depended on the type of tumour involved.

141. In Fournier it was highlighted that the diagnosis refers to the type of cancer, not the grade of growth. Type and speed of growth were not correlated. In Table 3 they put a tumour doubling time of 179 days in patients less than 50 years.

142. It was put to Prof. Bundred that the Lundgren paper was an old paper from 1977 and was based on a sample of only 15 patients. The witness stated that Table 1 showed that for a 38-year-old the appropriate tumour doubling time was 276 days. However one had to look at the individual factors of the tumour.

143. It was put to the witness that in the Sprat, May & Sprat paper which was from 1996, Table 4 showed that for patients aged 35 to 39 years, a tumour doubling time of 38 to 48 days was appropriate. The witness stated that in a lot of the papers different areas are general, but for each patient, one had to look at tumour specific factors for that patient.

III.IV Evidence of Dr. Marie Staunton

144. The plaintiff called Dr. Marie Staunton, Consultant Histopathologist, at Beaumont Hospital. Dr. Staunton was awarded her primary medical degree from NUI Galway in 1989. She has worked at consultant level since 1999. From 1999 – 2005, she worked as a Consultant Histopathologist in the Royal Victoria Infirmary in Newcastle Upon Tyne where she was the lead histopathologist for breast pathology. She has been working at Beaumont Hospital since 2008, where she is a member of the Breast Multidisciplinary Team, which plays a critical role in the diagnosis and prognosis for patients attending the Beaumont Breast Centre.

145. In the present case, Dr. Staunton prepared a histopathology report dated 26th August, 2016. This report was based on tissue, presented on slides, taken from an ultrasound guided biopsy which was carried out on the plaintiff on 23rd August, 2016. The slides display a snapshot of the biological processes of the cancerous breast tissue at the time the biopsy was taken, and allows for an assessment and grading of the tumour.

146. When examining the slides under a microscope, Dr. Staunton observed that the tissue bore no resemblance to normal benign breast tissue. Instead, she saw tumour proliferation, which had the features of an invasive carcinoma of a ductal subtype. "*Invasive ductal carcinoma*" means the cancer has invaded the fibrous, or fatty tissue, of the breast outside the duct. It can therefore gain access to the vascular system and potentially metastasise.

147. Dr. Staunton outlined the grading of tumours, which is known as the modified Bloom-Richardson grading system. A numeric score from 1 – 3 is given to three grading criteria, namely: Tubule Formation, Nuclear Pleomorphism and Mitotic Count. Each criterion is looked at objectively, independently assessed and assigned a numeric score based on the degree by which it has deviated from normal breast ductal cells. These scores are then added together to form a total score, which is used to determine the grade of cancer. Grading can range from Grade 1, slow growing tumours, to Grade 3, highly aggressive tumours. Most tumours are Grade 2, which is somewhere between slow growing and highly aggressive. Dr. Staunton accepted, however, that Grade 1 cancers have the potential to kill people, while people with Grade 3 cancers can survive.

148. Dr. Staunton explained the three grading criteria. Tubule Formation assesses what percentage of the tumour forms normal duct structures. Normal breast tissue has ducts with an open duct lumen. These structures are similar in appearance to tubes, and when halved, they look like donuts with holes in the centre. The more the tumour diverges from this norm, the higher the score will be. Lower grade ductal carcinomas have almost all tubule formation, and higher grade tumour have an almost completely solid growth pattern.

149. Pleomorphism is the variation in nuclear size. In normal breast cells, the nuclei are uniform and all grow and replicate in the same way. In an aggressive tumour, the cell nuclei are bigger, due to more DNA content, with the acquisition of mutations. The more the cells resemble the background breast cells, the lower the score for pleomorphism and the greater the probability to be a Grade 1 tumour.

150. Mitotic Count measures how many mitotic figures the pathologist can count. It is effectively a measure of the proliferation rate of the cancer. The mitotic rate is a measure of the number of cells undergoing mitosis i.e. cell division. A pathologist aims to get a representative sample of the tumour and counts the number of mitotic figures (structures in the tissue indicating cell division or markers of cell division) that are present in any given field. To arrive at a score, Dr. Staunton counted the number of figures she had seen over 10 fields. 1 – 7 figures would attribute 1 point, 8 – 14 figures would attribute 2 points, and 15 or more mitotic figures would be attributed 3 points.

151. The individual points from each criterion are then added up for an overall score and are given a corresponding grade to determine the grade of cancer. A score of up to 5 would receive Grade 1, a score of 6 or 7 would receive Grade 2, and a score of 8 or 9 would receive Grade 3. Dr. Staunton explained that based on the current material and the various criteria, the plaintiff "*probably*" had Grade 2 cancer based on the score of 3+3+1 for Tubule Formation, Nuclear Pleomorphism and Mitotic Count respectively. This was her opinion until the full tumour was removed and would be fully analysed post-surgery. However, that was never done. Hence she had used the word "*probably*".

152. The oestrogen and progesterone hormone receptor assessment is important in the treatment planning phase of the disease, rather than being required for a diagnosis. It carries prognostic information about the possible biological behaviour of the tumour, and also provides a therapeutic option for the medical oncologist treating the patient. The report is generated by using a special technique called immunohistochemistry, whereby a coloured antibody is used to detect the presence of either of the hormone receptor antigens in the tumour.

153. Dr. Staunton's report shows that the plaintiff was progesterone and oestrogen receptor positive, meaning the breast carcinomas were hormone driven. The growth of hormone receptor positive carcinomas can be stunted by blocking the amount of oestrogen in the body, by using anti-oestrogen therapies such as Tamoxifen. This will ultimately slow the growth of the tumour cells. She stated that hormone receptor positive tumours are generally less aggressive.

154. The histopathology report dated 23rd August, 2016 states that the plaintiff was HER-2 negative, meaning there was no point in

treating her with anti-HER-2 therapies such as Herceptin. Hormone receptor positive and HER-2 negative tumours, as is the case for the plaintiff, were consistent with Grade 2. As a general rule, hormone receptor positive and HER-2 negative tumours are slow growing.

155. Dr. Staunton stated that the ultrasound guided core biopsy of the left axillary node was similar in morphology to the tissue extracted from the breast. This meant that the lymph node contained metastatic carcinoma, which looked exactly the same as the carcinoma in the plaintiff's breast. Therefore, Dr. Staunton drew the conclusion that the cancer in the plaintiff's lymph node was the same as the cancer present in the breast tissue, and that it most likely originated from the breast cancer. Dr. Staunton stated that an unrelated secondary cancer in the lymph node was highly unlikely.

156. Dr. Maeve Redmond's histopathology report, dated 28th September, 2016 related to a lesion on the plaintiff's liver. It noted that the tumour found there was biologically the same as that found in the breast. Dr. Redmond's finding of the metastatic ductal carcinoma in the liver being CK7 positive and CK20 negative, was noted by Dr. Staunton as being very significant. It helped to predict the probability of the source of origin of this secondary tumour. Dr. Staunton stated that when you found a tumour which was CK7 positive and CK20 negative, in the setting of known breast carcinoma, then for all intents and purpose it was metastatic carcinoma of breast origin.

157. Dr. Redmond's report contained a supplemental report of Professor Elaine Kay. This referred to a supplemental test request for PD-L1 (Programmed death-ligand). The plaintiff's results revealed that a new category of drugs, which were available, would not work for her as she did not qualify.

158. Dr. Staunton also referred to the report of Dr. Christian Gulmann, dated 4th October, 2016. This related to a cytology specimen taken from the left paratracheal node. A small number of malignant cells showing similar features to the breast carcinoma were identified. They were found to be "*consistent with metastatic adenocarcinoma of breast origin*". Dr. Gulmann's report showed that the tumour cells were negative for TTF-1, which is positive in the majority of lung cancers, therefore indicating that the cancer located in the lung was not lung cancer, but rather cancer of breast origin.

159. Dr. Staunton further noted that apart from the grading of cancer, the cancer is also staged. When the plaintiff presented in 2016, the presence of a metastasis in her axillary lymph node brought about "*staging investigations*", before any surgery would be carried out. Dr. Staunton noted that, in this case the tumour was likely to have been there in 2014, as the biological type of tumour, i.e. hormone receptor positive and HER-2 negative, tended to be relatively slow growing.

160. The reference to "*cortical thickening*" in a lymph node was a radiological indication of an abnormal lymph node, and given the setting of a known or probable breast cancer on mammogram, prompted the radiologist to do a needle core biopsy to confirm or exclude metastatic cancer.

161. Dr. Staunton explained that there is a molecular classification scheme for breast carcinoma, which can only be accurately performed by gene expression profiling. It is not in routine practice. The molecular classification can predict the likely behaviour of tumours. Inferring from features such as the hormone receptor status and the HER-2 status, the plaintiff's tumour was likely to be a Luminal A type breast cancer, which should be, in theory, slow growing and less aggressive.

162. Dr. Staunton stated that when an oncologist is considering how a tumour might behave and what treatment would best suit the patient, they do not look at any one factor in isolation from that patient. Accordingly, they would not look at the histopathology report, or any component thereof, in isolation. She explained that the pathologist's role was simply to comment on what they saw under the microscope. Based on the scientific analysis of what they saw, they would give their diagnosis of what type of tumour it was. However, it was for the oncologist to form an opinion as to how the tumour was likely to behave in the future, based on the pathologist's report, and on other information relevant to the particular patient. Dr. Staunton's role was solely to give a scientific opinion based on what she could see and prove in the laboratory.

163. In cross-examination, Dr. Staunton stated that the three elements which went to make up the overall grading of a tumour, being Tubule Formation, Pleomorphism and Mitotic Count, were treated equally. The mitotic score was not given any special weighting. It was not more important than the other two criteria.

164. It was put to Dr. Staunton during cross-examination that Prof. Leen, Consultant Histopathologist for the defendant, had asserted in his report that a score of 3+3+1 was somewhat unusual, and may reflect delayed fixation. Dr. Staunton stated that she was aware of the procedures used in Beaumont Hospital for taking biopsies and preparing slides, which are then reviewed by the pathologists. She was satisfied that there was no delay in fixation on the part of the laboratory technicians who prepared the slides. She agreed that a delay in fixation could result in the mitotic count being falsely low, but that in the setting of biopsies carried out in Beaumont Hospital, delayed fixation was not an issue.

165. It was further put to Dr. Staunton that Prof. Leen was of the opinion that the "*the presence of high grade DCIS may indicate that a more aggressive clone was present within this tumour*". Dr. Staunton thought that this was speculation on his part as the entire tumour had not been available for analysis. She reiterated that the role of the histopathologist was merely to analyse and comment on what they saw before them under the microscope. Commenting on Prof. Leen's assertions would be speculation on her part.

166. Dr. Staunton was asked to comment on Prof. Leen's assertion that "*if the tumour was node positive back in 2014, this scenario would suggest very significant and persistent nodal disease unlikely to have remained occult for two years*". She further declined to comment on this, as it would be speculation on her part.

167. In the course of cross-examination, it was put to the witness that in a letter written by Prof. Morris, he had stated that the plaintiff's tumour had behaved "*like an aggressive tumour*". This implied that one had to consider how the particular cancer has behaved in a particular patient. Dr. Staunton agreed with this assertion.

168. Dr. Staunton was of the opinion that this was a fairly aggressive tumour. Proof of its aggressive behaviour, was the fact that the plaintiff had metastatic disease. It was clear from the progression of the disease that the tumour was fairly aggressive.

169. Evidence was also given on behalf of the plaintiff by her husband and by Prof. Morris. This evidence was primarily directed to issues of quantum.

IV. Summary of Evidence on behalf of the Defendant

IV.I Evidence of Dr. Norma Donlon

170. Dr. Donlon, the defendant in this case, graduated from Trinity College Dublin in 1998. She then did an internship year in Tallaght Hospital, and in 2001 she became a member of the Royal College of Physicians in Ireland. After that she went to the United Kingdom where she completed a GP registrar year, followed by membership of the Royal College of GPs. She began working at the Hilltop Surgery, Raheny, Dublin, in 2004.

171. With regards to the general procedure at the clinic for making appointments, Dr. Donlon explained how there were two receptionists working at the clinic, who would answer the phone and write down the appointment into a handwritten diary or appointment book. Then they would enter it into the electronic diary, where all appointments would be logged and you could see all the appointments that were booked for the day. When Dr. Donlon, or other doctors at the clinic, would open up their computer, the electronic appointment diary appears on their computer. It would show a patient's name and an appointment time.

172. The consultation on 24th September, 2014, was on a Wednesday. The defendant usually worked all day Monday and Tuesday, and Friday mornings. On that particular day she was probably covering for Dr. O'Connor. She did not recall what exact notice she had been given that she would be working that day. Her normal start time was 15:00 hours. She had no recollection of anything specific concerning the patients that she had seen that day. Usually she would take a quick look at the patient's chart on the computer prior to calling them in. She would look at the patient summary box, which would detail any ongoing chronic diseases and give a summary of the medication that she was on. She might also look at the previous visits to the clinic.

173. She had not seen the plaintiff previously as a patient, but she had a recollection that she may have met her on a previous occasion, when she came with one of her children. She went out to the waiting room and brought the plaintiff into the consultation room. The defendant said that she sat at her desk and the plaintiff sat on a chair to the side of the desk. The plaintiff's file was open on the computer. She asked the reason for the visit, to which the plaintiff said that she was concerned about a lump under her arm. The defendant had no recollection of breast cancer being mentioned, other than when she asked the plaintiff if there was any family history of breast cancer. If she had mentioned a concern about breast cancer, she would have recorded that.

174. When taking the history from the plaintiff, she would have asked for descriptive factors of the lump such as its size, shape, whether it was tender, the location of the lump, the duration of the lump, and whether it had been there previously. She would only record any relevant positive or negative details. These questions were asked while the plaintiff was sitting at the desk and she was sitting at the computer. This was the history taking phase of the consultation.

175. She was relying on her note, which stated that the plaintiff had said that the lump was non-tender and it had been present for approximately three months.

176. The next phase was her examination of the plaintiff. She asked the plaintiff to sit on the edge of the bed and to bear her arm. She could not recall what the plaintiff was wearing that day. She may have removed her outer top, but not her bra. She did not ask the plaintiff to lie on the bed at any stage. She was sitting on the edge of the examination bed. The plaintiff would have to lift her arm to show her the location of the lump. However the examination itself was done while she was supporting the plaintiff's elbow and holding the arm slightly abducted from the body. This was necessary to ensure that the muscles in the upper arm and in the armpit were lax, thereby enabling a proper examination of the axilla. This was the method that they had been taught to carry out such examinations. In carrying out the examination she used the tip of her fingers to palpate the entire area of the axilla, being the walls and the apex of the axilla.

177. Having examined the axilla, she was unable to find any lump. She would have asked the plaintiff to point out where she thought the lump was and she then palpated the entire area again. She could still not find any lump. The defendant stated that she would have told the plaintiff that she could not find any lump in the axilla. The plaintiff did not give her any sense that she thought that the lump was still present. She did not communicate any such belief to her. She then examined the right axilla to ascertain if there was any lump present there and for comparative purposes. She had written the word "axillae" in her notes.

178. When she had completed the axilla examination, she would have suggested that a breast examination would be done. She would have used words to the effect "I would like to perform a breast examination". She would try to keep the request in a conversational tone, as this was her first time seeing the plaintiff.

179. The defendant stated that she wanted to do a breast examination, as that was part and parcel of the examination of the axilla. At that time she had not found anything in the axilla and the index of suspicion of breast cancer was low, due to the plaintiff's age and the absence of any family history of breast cancer, but a breast examination was still advisable. The defendant said that she could not recall the exact words used by the plaintiff, but she did have a recollection that her request was declined. That seemed unusual to her. She had no doubt that she had made the request and that it was declined.

180. The defendant stated that when the plaintiff declined the breast examination, that was a difficult situation. There can be reasons why a patient would refuse such an examination. She did not feel that she could push a breast examination at that time. She did not sense any unease or disquiet on the part of the plaintiff. If there had been she would have documented it. If there had been some disquiet on the plaintiff's part, that would have stood out.

181. When the examination was complete, the patient would get dressed and the defendant would sit at her desk. There would then be the discussion phase of the consultation, where she would give her impression of a possible diagnosis and they would discuss a management plan for the future. It was put to the witness that the plaintiff had said that the defendant had assured her that someone of her age would not get breast cancer. The defendant stated that she would not ever give such a blanket assurance, as no doctor could reassure someone that they would not get cancer. The reference to "reassurance" in the notes, meant that she had reassured the plaintiff that she could not find any lump in her axilla and that inflammation of the lymph nodes could have been due to her eczema. She stated that whatever was written in her note had definitely been verbalised with the plaintiff.

182. The defendant stated that when she had confirmed to the plaintiff that she could not find any lump in the axilla, she had no sense of any divergence of opinion between her and the plaintiff in relation to the presence of the lump. If the plaintiff had maintained that the lump was still present, she would have noted that and the consultation would have gone in a different direction. She would have advised the plaintiff to return in a couple of weeks and she would have examined the axilla again. If there was still disagreement as to the existence of the lump at that consultation, she would probably have referred the plaintiff for an ultrasound scan.

183. She explained that portion of her notes which read "impression -? Resolved LN secondary to eczema" as meaning, that she would have told the plaintiff that she could not find any lump. That she noted that the plaintiff had had long-standing eczema and that she felt that it was probably a transient lymph-node secondary to eczema. The final part of her note recorded her advice to the plaintiff

that she should return to the clinic if the lump recurred. This suggested to her that both she and the plaintiff were in agreement that the lump was not present that day. However, it was important that a patient should know that if the lump recurred, they should re-present to the surgery.

184. The defendant stated that her notes were written up immediately after the plaintiff left her consultation room and before the next patient was called in.

185. It was put to the defendant that the plaintiff's expert had suggested that she should have told the plaintiff to return for further examination in 4 to 6 weeks. The defendant stated that she had been satisfied that there was no lump palpable and she was further satisfied that there was a plausible explanation for the transient lump. For that reason, she did not tell the plaintiff to return in a number of weeks. However the plaintiff understood that she was to return to the surgery, if the lump should recur.

186. She next saw the plaintiff in December 2014 in relation to infection of her eczema. There was no mention of the previous consultation, or of the axilla lump at that consultation. If the plaintiff had said that the axilla lump was still present, the defendant stated that she would have examined the axilla again and if the plaintiff still maintained that the lump was present, she would probably have referred her on for an ultrasound scan of the axilla.

187. The defendant saw the plaintiff again in relation to unrelated matters in July 2015 and July 2016. Again there was no mention of the axilla lump.

188. The defendant stated that she had no doubt, or sense that the plaintiff had left the consultation in September 2014 with any sense of unhappiness or disquiet. If there had been, she would have documented it.

189. In cross examination, the defendant accepted that early detection of breast cancer was important. She accepted that women are encouraged to go to their GP if they find a breast lump. She was not sure if they would be given such encouragement if they found a lump in the axilla. This was because there were many reasons for a lump in the axilla.

190. However, she accepted that a woman who found a lump in her axilla, should get it checked out. She accepted that on the Internet there was advice that an axilla lump could be connected to breast cancer.

191. The defendant accepted that many women, if they were due to have a breast examination, would specifically choose to go to a lady GP. She accepted that it would not be unusual for the plaintiff to come to see her rather than Dr O'Connor, if she thought that she might have to have a breast examination.

192. In relation to the notes of the plaintiff's prior visits, the defendant stated that when she looked at the computer in 2014, she would only have had sight of the notes kept by the doctors at the Hilltop surgery, as the notes from the Raheny surgery were not amalgamated until after 2017. The Hilltop notes showed that the plaintiff had a history of asthma, eczema and soft tissue injuries from an RTA in 2008. Her last visit to the surgery had been on 20 August 2014 when she had complaints in relation to her eczema, but no infection was found.

193. It was put to the witness that there was no history of inflammation of her lymph nodes in the notes. She agreed that that was so, but there was no note that the lymph-nodes had been checked. She accepted that there was no prior complaint in relation to inflamed lymph-nodes, notwithstanding that the plaintiff had had eczema for many years.

194. In relation to the consultation on 24 September 2014, the defendant accepted that her only recollection of that consultation was that there was no conversation concerning breast cancer, other than her question in relation to any family history of breast disease. She also had a clear recollection that a breast examination was declined by the plaintiff. Other than those matters, she had to rely on her contemporaneous notes.

195. It had been recorded by the defendant that the plaintiff had been concerned about an axillary lump for three months. She accepted that that was a long period of time. However it was possible that if it was caused by eczema, it could last that long, depending on the size of the lump and the treatment that had been given. She accepted that no treatment had been given when she was seen in August 2014. However eczema was a recurring condition. It was put to the witness that if her eczema had recurred, it was reasonable to assume that she would have returned to see Dr O'Connor. The defendant stated that often people with eczema would not go to their GP, as it was a chronic condition. However she accepted that if the plaintiff had had a particular problem with her eczema, she would probably have returned to see Dr O'Connor.

196. It was put to the witness that as she had not returned to see Dr O'Connor after August 2014, it was reasonable to assume that there was no information in the lymph-node caused by eczema. The defendant stated that inflammation in the lymph-node could be caused by other things. Also the lymph-node had not been checked in August.

197. It was put to the witness that when she had seen Dr O'Connor in August 2014 in relation to eczema, the plaintiff had not mentioned the lump in her axilla, which according to the plaintiff was in existence at that time. The defendant stated that she may not have associated the axilla lump with her eczema. She would not expect a patient to make that connection.

198. The defendant accepted that the plaintiff's concern at presentation in September 2014 was in relation to an axillary lump. The aetiology of that in the plaintiff's mind was not clear. However she accepted the plaintiff's evidence that the plaintiff had a concern due to her Internet search, that there may be a connection between the lump and breast cancer. It was put to the witness that the only reasonable explanation was that she had attended with the defendant because of a concern in relation to a lump in her axilla and the possible connection with breast cancer. The defendant stated that if the plaintiff had told her that she was concerned about breast cancer, that would have been documented. She did not accept that because the plaintiff may have looked at the Internet and seen a possible link between the two, she would definitely have mentioned it to her. Often patients can have a concern about something, but that may not be communicated to their GP. She had asked the plaintiff why she had attended the surgery and the plaintiff had said that she was concerned about a lump under her arm. Because not all lumps are connected to cancer, she may not have said that to the GP. It was put to the witness that here was a young lady, who had a lump under her arm for three months and had done an Internet search showing a possible link to breast cancer and in such circumstances it was suggested that it would be odd that she would not mention her concern in relation to breast cancer. The defendant reiterated that if there had been an expressed concern in relation to breast cancer, that would have been documented in the notes.

199. The plaintiff had said that the lump was non-tender. The defendant accepted that that indicated that it was not infected. So she had reported a non-tender lump present for three months meaning that it was probably not an infectious lump. It was put to the

witness that that would take it out of the realm of a lump caused by eczema. The defendant did not agree. Lumps connected to eczema would come and go as the disease itself waxed and waned. She did not think it unusual that it had lasted three months. The lump can be transitory. One can have lymph adenopathy independent of infection as part of eczema.

200. The defendant stated that on this occasion the plaintiff had not mentioned any breast lump. She had come to the surgery with the complaint concerning an axillary lump. Accordingly she did not jump into a cancer conversation with the plaintiff. If a patient had told her that they were concerned in relation to breast cancer because of the axillary lump, one would go through the history of the lump and the patient's family history and then do an examination of the axilla, followed by a breast examination.

201. It was put to the witness that if the patient was a young lady, would she not have said that it was unlikely that young ladies would have cancer. The witness denied that. She said that she would take a full history. Then do an examination leading to certain findings. If no axillary or breast lump was palpable and it was a young woman with no family history of breast disease, then she would tell the person that at 35 years the index of suspicion for breast cancer was low. She would not tell them that in most cases breast cancers were only in ladies over 50 years. She did not reassure the plaintiff that she was unlikely to have breast cancer being in her early 30s. She would only give that reassurance to young women, if there was no lump palpable in the axilla or the breast and no family history of breast cancer. If a person came in concerned about breast cancer, that would be documented in the notes, so that they could formulate an appropriate management plan.

202. The defendant stated that while she did not recall the exact words used at the consultation, if the plaintiff had still felt that there was a lump present at the end of the consultation, it would have taken a different path. The defendant stated that if the plaintiff thought that the lump in her axilla was still present, she did not communicate that to her. She had told the plaintiff that she could not find any lump. Her note suggested that the plaintiff agreed that there was no lump present at that time.

203. The witness was challenged on this, as counsel stated that it had not been put to the plaintiff that she had specifically agreed that there was no lump present. The defendant agreed with that assertion. However she reiterated that if it had been communicated to her that the plaintiff could still feel a lump, the consultation would have gone differently. She stated that there was no sense of discord or disagreement between them in relation to the absence of the lump at that consultation.

204. She was asked why she had not recorded that the plaintiff agreed that there was no lump present. The defendant stated that that would not be routinely recorded. In her view, consensus was implied in the note that she had written. She had recorded her findings on examination of the axilla.

205. It was put to the witness that it would be highly unusual for a woman to attend with her GP if the lump had actually gone or disappeared. The defendant disagreed, stating that it was not uncommon, that if a lady had had a lump in previous weeks, she might still go to her GP in relation to it. It was put to her that the note did not say that she had had a lump for the previous months, but that it had gone at the time of the consultation. The defendant accepted that her note did not state that. She accepted that the plaintiff had told her that she had a lump for three months and it felt non-tender. It was put to the witness that it was extraordinary to suggest that a patient would come in in relation to a lump that had disappeared. The defendant stated that that was not unusual.

206. She could only say that there was no lump palpable by her at that consultation. She had had situations where patients would complain of a lump, but she would not be able to find one on examination. The axilla was not a complex area to examine. If there was a lump there, she would usually be able to find it. While she agreed with the opinion of Dr Burton that a patient can have a sense of their own body, she did not agree that they could feel the lump when a doctor could not find the same lump on palpation. Occasionally a patient might feel something that was not in fact significant and the doctor would be able to reassure them in that regard.

207. She accepted that for a lady to come in with a concern in relation to breast cancer, but to decline a breast examination, would be very unusual. She had thought that she ought to examine the plaintiff's breasts. The situation was that there had been no finding in the axilla, there was a long history of eczema, this was a 32-year-old patient with no family history of breast disease, so the index of suspicion for breast cancer was low and in addition, she had a plausible explanation for inflammation of the lymph nodes.

208. The defendant was asked whether in such circumstances she would remonstrate with the plaintiff in relation to the need to do a breast examination. The defendant stated that one had to look at all the circumstances: there was no lump in the axilla; no family history of breast disease; the patient had eczema and it was the first time that she had met the plaintiff. Accordingly, while she had requested to do a breast examination, she did not take it any further, when that was refused. She had documented the patient's refusal to have such an examination.

209. While a breast examination was the preferable course, there had been no axilla lump palpable. Such examination was offered and had been declined by the patient in circumstances where the index of suspicion for breast cancer was low.

210. The defendant stated that cancer had been in her mind, or on her radar at that consultation. She had asked a question about there being any family history of breast cancer. However, she had not had a broad cancer conversation with the plaintiff. She had only asked if there was any family history of breast cancer, which was asked in the context of the presenting factor, which was a lump in the axilla, which she accepted could be connected to breast cancer. It was put to the witness that here, there was a young lady in her early 30s, there had been some discussion in relation to breast cancer and in these circumstances, was there any reason for her to refuse a breast examination. The defendant stated that she could not think of any rational explanation for such refusal. She accepted that such refusal was very unusual.

211. It was put to the witness that the offer and refusal had not happened and that she had tried to misinterpret her own notes. The defendant agreed that it was unlikely that the lady would refuse a breast examination, but it was not impossible. She was asked whether that would have rang alarm bells with her. She stated that the current presenting complaint had been an axilla lump. She had mentioned breast cancer in the context of family history, but did not have any wider discussion in relation to cancer. She accepted that breast cancer had been on her checklist because it was a very serious condition, but was very unlikely in the context of a presentation with an axillary lump. She had offered a breast examination for completeness, but it had been declined.

212. It was put to the witness that she had reassured the plaintiff that she was too young for breast cancer and that such disease was usually in people in their 50s and that on that account, she had left the consultation delighted. The defendant stated that she never gave any broad assurance in relation to cancer. It was not possible to give such reassurance. She had reassured her that she had not found any axilla lump and that there was a plausible explanation for that. She had concluded that the lump was probably a transient complication of the plaintiff's eczema.

213. It was put to the witness that she had made a probable diagnosis that the lump was connected to the plaintiff's eczema, when there was no prior history in the notes of any such lumps being connected to her eczema. The defendant accepted that her diagnosis of probable lymphadenopathy connected to eczema, was the first time that that had been diagnosed for the plaintiff. However, she stated that eczema was a chronic process. A common cause of lymphadenopathy, would be a chronic condition such as eczema. Although she accepted that that had not been recorded in the plaintiff's notes previously. However if she had had such nodes previously, it may not necessarily have been recorded in those notes, because the nodes may or may not have been palpable and they would wax and wane over time. Her impression was that the plaintiff had had transient lymph-node inflammation connected to her eczema, which had disappeared by the time that she had seen the plaintiff.

214. It was suggested to the witness that that theory was highly improbable. She disagreed, stating that transient lymph adenopathy was commonly connected to eczema. She accepted that it might have recurred over the time that the person had flare-ups of her eczema; a lot would depend on the treatment being given. It may or may not have presented before. It was put to the witness that that theory was highly improbable, given that the plaintiff had not presented with such complaint connected to eczema prior to 2014. The defendant stated that in the context of no lump being palpable in a young person, with no family history of breast cancer and given that swelling in the axilla was not usually the first sign of breast cancer, she felt that the eczema was the most likely explanation for the lymph adenopathy, but with the caveat that the patient should return if the lump recurred.

215. On 12th December, 2014, the defendant saw the plaintiff again with impetiginised eczema. She did not examine the axilla on that occasion. She was satisfied that there had been no lymph-node palpable in September 2014. There had been a plausible explanation for that. She had given guidance to the plaintiff to return to the surgery if the lump recurred. There had been no dispute in relation to that. She accepted that the plaintiff had returned in December 2014 with infected eczema and that an inflamed lymph-node can be part and parcel of that. However, she would only check the axilla if there was a complaint made in relation to that area.

216. She accepted that she had not made any reference to the plaintiff's prior refusal of a breast examination. She accepted that that had been unusual and that she would have liked to have done a breast examination in September 2014. However there had been no lump palpable in the axilla, there was a possible explanation for that and the plaintiff had agreed to return to the surgery if the lump recurred. The plaintiff had not mentioned either the lump, or the breast examination in December 2014 and nor did she.

217. It was put to the witness that she might have told the plaintiff at that consultation that she was being a bit foolish to refuse a breast examination and that it would only take a minute to do. The defendant stated that she did not think that it was necessary to reopen the issue, unless the issue of a lump was presented to her. She denied that she had dismissed the lump in relation to a risk of cancer, as there had been no lump palpable in September 2014.

218. It was put to the defendant that if she had dismissed the lump in September 2014, that would explain why the plaintiff had not mentioned it subsequently. The defendant stated that she had not dismissed the lump. She had not found any lump. She had given specific reassurance that there was no lump palpable and advised the plaintiff to return if the lump recurred.

219. She had seen the plaintiff in July 2015 in relation to injuries arising out of her RTA. There was no reference to the lump, or to the refusal of a breast examination at that time.

220. In re-examination, the defendant reiterated that if the plaintiff had returned to her and still maintained that she had a lump in her axilla, and she could not find it, she would then have referred the plaintiff for an ultrasound scan of her axilla. She also reiterated that inflammation of the lymph-node was not synonymous with infection.

IV.II Evidence of Dr. Ronan Boland

221. Dr. Boland commenced by giving evidence of his qualifications and experience. He is currently principal partner in a busy GP practice in Cork city. It is a two doctor practice, with one nurse. He frequently does breast examinations. Many of his patients do not mind coming to him for such examinations. He would do an average of 2/3 breast examinations per week. He was a former president of the Irish Medical Organisation.

222. Dr. Boland said in summary, based on his assessment of the defendant's account of events and the content of her contemporaneous notes, he was of the view that she had acted in a way that most competent GPs would have done in the circumstances.

223. Dr. Boland stated that a GP's note was primarily an aide memoir when treating a patient on an ongoing basis and was also of assistance if there was any subsequent dispute as to what happened at the consultation. The note was necessary when the GP was seeing 4 – 6 patients per hour, which could be 25/30 patients per day. The note was also necessary if the patient should be seen by other doctors in the practice later on.

224. He thought that the defendant's note in this case was an acceptable note. It was put to him that the plaintiff's expert, Dr. Burton, thought that the note was adequate, but not detailed. Dr. Boland stated that any note could always be more detailed. It was necessary to record what happened at the consultation, while not taking away from the time that one had with the patient. It was necessary to strike a balance, given that one was seeing 25/30 patients per day, one had to be practical. He thought that the defendant's note was a good one.

225. It was clear from the records that the plaintiff had chronic eczema. The defendant had noted that the plaintiff was concerned in relation to a possible axillary lump, which had been present for three months. A lymph node could be inflamed by infection, but it could also happen in the absence of infection. One can have either inflammation or infection as the cause of enlargement of the lymph node. If a patient had a flare-up of eczema, they could have lymphadenopathy. This could be transient, or it could persist. The fact that it had a duration of three months, was not a red flag in itself. It may not have been continuous for the entire three month period.

226. The note made by the defendant indicated that she had worked through a number of likely differential diagnoses, one of which low down on the list was breast cancer, which she had considered. With an axillary lump the connection to breast cancer was very small. For every one lump that was connected to breast disease, there would be hundreds which would be due to gland secretions.

227. Dr. Boland stated that if the defendant had said "I would like to examine your breasts", that would be adequate. Generally the examination should be not offered in a way that would alarm the patient, as it was only being offered for completeness sake, in circumstances where no axillary lump had been found. When clinical examination of the axilla had been negative, a breast examination would be offered for completeness sake. According to the defendant, the plaintiff had refused such examination and that had been documented. Dr Boland thought that that was all the GP could have done in the circumstances.

228. If the axillary lump had been found, then it would have been necessary to explain to the patient why an examination was not just prudent, but was necessary.

229. In a consultation the first phase is to take a history from the patient. The next phase is to do an examination. If both axillae had been examined and nothing was found, that would be all that he as a GP would have noted down.

230. Dr. Boland explained that to perform an axillary examination, ideally the plaintiff would be in the seated position, with the weight of the arm supported, so as to release the muscles of the axilla to enable palpation of the area. He thought that most GPs would just document findings that were positive or negative on examination. They would not document how the examination had been carried out.

231. Dr. Boland stated that communication with the patient was a big part of GP training. They are taught to pick up both verbal and non-verbal cues from a patient. The management plan was a joint plan with the patient. If a patient was uneasy with the GP's findings, or with their advice for future management, it would be necessary to tease that out, so as to try to achieve consensus with the patient. If a patient was not happy, then the issue was not resolved. If a patient was happy with the management plan advised, that would not be documented. However if the patient was not happy, the GP would be more likely to record that because the patient would be leaving unhappy with the outcome of the consultation.

232. In relation to the advice noted "TCI if recurs", he thought that that was an adequate safety net in circumstances where a GP had done a normal examination and the plaintiff was happy with the outcome of that. It left the door open to the patient to return if he or she saw fit. Here the plaintiff had said that she left the consultation relieved that there was nothing to worry about. That reconfirmed his view that the advice to return to the surgery if the lump recurred, was the appropriate advice to give. It was put to the witness that the plaintiff's expert, Dr. Burton, thought that the plaintiff should have been advised to return in 2/6 weeks. Dr. Boland stated that on the plaintiff's history on presentation and on the findings on clinical examination and as there did not appear to be any disagreement on the part of the plaintiff on those findings, he would not have brought the patient back for review.

233. If there was disagreement with the plaintiff when she came back the second time, that would cause the doctor to take further notice and to do a further examination and if nothing was found on examination a second time, and the patient was not reassured, then he would have taken further action in the form of a referral for an ultrasound, or a referral to the surgical OPD.

234. If there was no consensus in relation to the presence of the lump at the first consultation, some further follow-up would be indicated, either with the same doctor, or with another doctor within 2 – 4 weeks. He would not make a referral at that stage. If at the second consultation, the axilla examination was negative and the patient refused a breast examination, he would refer the patient for imaging of the axilla and make a surgical referral. They would take a holistic view. That would be in the OPD. He would not refer the patient to the breast clinic.

235. In relation to the GP guidelines, page 2 was the most important page. It sets out the circumstances in which a referral should be made. Page 1 deals with the urgency of the referral. In relation to the box headed "*Breast Lumps*" on page 2, Dr. Boland did not think that that referred to axillary lumps, subject to the caveat that the tale of a breast cancer can extend partially into the axilla. If the lump was not in that area, it would not be within that algorithm. The guidelines stated that if no lump was found in the breast, the doctor should "*Reassure ?Reassess*", meaning that the patient can be reassured, but it is left to the doctor's clinical judgement whether a review is needed.

236. Page 1 of the guidelines dealt with the circumstances in which an urgent referral should be made. It stated that if a discrete lump was found in the axilla, or breast, in a person under 35 years, an urgent referral should be made. A large percentage of axilla lumps would have nothing to do with breast cancer and would not need to be referred.

237. Dr Boland did not think that the guidelines were relevant in this case. They would not be relevant until it was established either in the patient's history, or on clinical examination that there was a breast problem. Here the presenting problem was an axillary problem, with nothing found on clinical examination of the axilla. Such examination would ideally have involved an examination of the breasts.

238. In relation to the plaintiff's subsequent visits to the defendant, Dr. Boland stated that unless there was a lack of agreement at the first consultation as to the presence of the axillary lump, or some uncertainty in the matter, most GPs would feel that the matter had been satisfactorily concluded on 24 September 2014 and would not have reopened the issue at a subsequent visit, unless the patient raised a specific concern.

239. Dr. Boland stated that he had seen lymph adenopathy as a result of breast cancer, but not as a presentation of it. As a GP, he would have been aware of the plaintiff's eczema condition. That would have been a plausible explanation for her complaint. As long as the doctor had done an examination to rule out other things, then they can act on the balance of probabilities as to the cause of the inflammation of the lymph-node. It was pointed out that in his evidence, Dr. Burton had said that on the notes he would not have expected to refer back to the axilla complaint on subsequent visits. Dr. Boland agreed with that analysis.

240. In cross-examination Dr. Boland stated that his opinion had been based primarily on the accuracy of the GP's contemporaneous notes. If the plaintiff's account was accepted by the court, then he would have criticism of the defendant's conduct. If the plaintiff had presented with a concern about breast cancer and the defendant had discussed those concerns with the plaintiff and yet did not offer a breast examination and then documented that the plaintiff had refused such an examination, he would be critical of those actions on the part of the defendant.

241. He accepted that if a patient had attended the surgery worried about breast cancer and had an expectation that there would be a breast examination, there would be no reason not to do one. A breast examination was a straightforward examination, which would take approximately 3 – 4 minutes.

242. It was put to the witness that Dr. Burton was of the view that if a doctor's actions were highly dependent upon clinical examination, it was necessary to proceed very carefully. Dr. Boland agreed with that. It was further put to the witness that in her evidence the plaintiff had stated that she had found the lump under her arm when in the shower. When it was there for a few months and after having done an Internet search she then became worried. He accepted that that was not untypical.

243. He accepted that an Internet search would show a possible link between a lump in the lymph nodes and breast cancer. He accepted that it was reasonable in those circumstances for the plaintiff to request that she be seen by a female GP. He accepted that she had had two children and so would have had intimate examinations in the past. He also accepted that if a person was

worried about breast cancer, they would probably expect a breast examination when they attended with their GP.

244. It was put to the witness that the plaintiff stated that the defendant had said to her that in general she was unlikely to have breast cancer at the age of 32. Dr Boland stated that he would not have used those words. He would not say to any patient that there were too young to have breast cancer, but he would reassure such a patient that it was unlikely at such a young age.

245. It was put to the witness that in her evidence the plaintiff stated that she had tried to show the GP where the lump was, as she could feel it. The GP examined the area again, but could not find it. Dr. Boland accepted that that was the type of thing that could reasonably happen. The plaintiff's evidence to the effect that the defendant had said that people in their 50s were more likely to have breast cancer and were more likely to be called for mammograms, was a reasonable statement in general.

246. Dr. Boland was asked as to the circumstances in which a patient might refuse a breast examination. He said that this could occur if a patient was seeing a male GP, or if she had not expected a breast examination on that visit, or if she was wearing unsuitable clothing, or it was possible that she may not have expected such an examination and may be embarrassed if it was late in the day and she was sweaty or unclean in the area to be examined. These were circumstances in which a patient might refuse such an examination.

247. Dr. Boland accepted that where a female patient specifically made an appointment to see a female GP and if she expected a breast examination, it would be very unusual for her to refuse such an examination.

248. It was put to the witness that patients do not normally make an appointment in respect of a lump that had gone. Dr. Boland stated that a patient may be concerned about an issue for some time, particularly if it tended to wax and wane. They might then grab the bull by the horns and make an appointment to see the doctor. If the lump had been waxing and waning over a period of three months, the patient might think that they better get it checked out. He accepted that if the lump was completely gone, it would be unusual for a patient to make an appointment to see their GP. He accepted that the defendant's note did not say that the lump had waxed and waned.

249. Dr. Boland did not agree with the evidence given by Dr. Burton that one would normally expect a more detailed note in relation to the history of the lump, its size, et cetera. Dr. Boland thought that the note made by the defendant was better than average. It was certainly as good a note as the majority of doctors would have made on that presentation. The note is only a note of the key relevant findings. It may not record all the questions asked by the doctor. He accepted that there was no reference in the note to the shape of the lump. However he would not normally ask the patient about the shape of an axilla lump. He accepted that there was no reference to whether the lump had been present in the axilla before. There was a reference to the lump being non-tender. He thought that the note accurately reflected the doctor's account of the consultation. He would not normally record whether there were lumps elsewhere, unless the patient had specifically reported lumps elsewhere in the body. He agreed that the questions suggested by Dr. Burton were reasonable. He pointed out that Dr. Burton had accepted that the defendant's note was an adequate note.

250. It was put to the witness that the defendant had stated in her evidence that she had asked questions in relation to the lump, such as how big it was, where it was, whether the plaintiff had had it before, and were there lumps elsewhere. Dr Boland stated that those were reasonable questions. However, how much you would record in the note, would depend on the answers given by the patient and the findings on clinical examination. If the findings on examination were positive, then one would set out all the relevant facts in a referral letter. He accepted that the majority of those questions should have been asked.

251. Dr. Boland also accepted that the plaintiff's evidence had been that the lump had been present continuously for the preceding three months. He accepted that there was no record of the lump waxing and waning, but there was a question mark over the possibility of the lump being there.

252. He reiterated that the GP guidelines in relation to breast cancer did not apply to this consultation because the plaintiff did not have symptoms or findings of breast cancer, so there was no basis for a breast referral. If the defendant's note was accurate the breast guidelines would not apply in this case. He did not agree with Dr. Burton's evidence that the guidelines at page 2 referred to both axillary lumps and breast lumps. Both he and the defendant had the same opinion in this regard and they were the doctors who operated under the Irish guidelines Dr. Burton would operate under the NICE code in the UK. There it was possible to get a referral within two weeks, whereas in Ireland it could take up to 6 months for an urgent referral. Accordingly Irish GPs had to be pragmatic which patients they would refer for urgent referral.

253. Dr. Boland agreed with Dr. Burton that in principle if the doctor could not find a lump in the axilla, but if the patient thought that the lump was there, then one should reassess the patient. If the patient agreed that there was no lump present, then it was only necessary to give reassurance. It was put to the witness that Dr. Burton had stated that if the patient thought that the lump was still there, the GP should either reassess or refer. Dr. Boland did not agree that there should be a referral at the first visit if there was disagreement; there should just be a reassessment after a few weeks. This was necessary because there was no consensus, but a referral at that stage would not be appropriate. The review should take place 2 – 6 weeks later. If on the second occasion the patient still thought that there was a lump, then a referral would be appropriate, even if only to reassure the patient.

254. It was put to the witness that Dr. Burton had stated that if one found an axilla lump and a lot of eczema, it would be appropriate for the GP to treat the eczema. Dr. Boland agreed that if there was inflamed eczema, it would be reasonable to treat that and then reassess the plaintiff, or tell the plaintiff that if the lump was still there after treatment, she should return. One would treat the eczema with antibiotics and steroids. Dr. Boland accepted that if the patient remained concerned about a lump, then the option of referral moves up the ladder.

255. Dr. Boland stated that if a GP was doing an axilla examination, he would always want to do a breast examination as well for completeness sake. If no breast examination was done at the first consultation, if on the second occasion the patient still thought that there was a lump present, the GP should be more vigorous in seeking to do a breast examination. The doctor should go into detail as to why a breast examination was necessary. The doctor would try harder on the second occasion to carry out such an examination. He accepted that it would be highly likely that a patient would consent to such an examination in those circumstances.

256. In terms of how he would put the request, Dr. Boland stated that he would say to the patient "*For completeness sake I would like to do a breast examination*" or "*It would be prudent to do a breast examination*". Those words would be appropriate because the index of suspicion in the absence of a positive axilla examination was low. In such circumstances, the doctor would not pursue the issue of a breast examination more vigorously. If the patient returned on the second occasion, then he would be more vigorous in relation to the request for a breast examination.

257. On the defendant's note, after a negative axilla examination, there would be a very low index of suspicion for breast cancer. The doctor would still do a breast examination for completeness, but would not push a refusal of such examination by the patient.

258. It was put to the witness, that if the plaintiff had been reassured that there was nothing to worry about, that would explain why she had not mentioned it at subsequent visits to the doctor. Dr. Boland accepted that that could explain why the plaintiff had not mentioned it when she had returned to the doctor.

259. In re-examination Dr. Boland stated that there was always a departure phase to the consultation. This was used to tie things together. The GP had taken a history from the patient, had carried out an examination and had formed a diagnosis and a treatment plan. The diagnosis and treatment plan would be discussed with the patient and agreed upon. This will include any advice in relation to whether the patient should return for review. This phase would include an assessment of whether the patient was in agreement with the diagnosis and the treatment plan.

260. "*TCI if recurs*" meant that the GP had not been able to find the lump. While the note did not specifically state that the plaintiff was in agreement, most doctors would not record a consensus. Consensus between doctor and patient would be implied, unless documented to the contrary. When the GP could not find the lump in the axilla and it was presumed that the plaintiff agreed with that assessment and she was advised to come back if the lump should return, then that was reasonable advice to give in the circumstances.

IV.III Evidence of Professor Pat Price

261. Prof. Pat Price was called to give evidence on behalf of the defendant. She is a qualified doctor with a research degree from the University of Cambridge on growth rates of tumours. She is a Fellow of the Royal College of Physicians and the Royal College of Radiologists. She is a clinical oncologist, and a specialist in cancer treatment. She has spent the last 30 years of her research career looking at the measurement and the assessment of growth rates of tumours and their response to therapy.

262. Prof Price began by explaining the term "mild cortical thickening" as being an indication in a lymph-node which was not obviously malignant, that there was something which would give rise to a suspicion that there may be malignancy present, hence the need to do a biopsy. The biopsy enabled the diagnosis to be made that there was disease in that node. In these circumstances the assumption would be that the mild cortical thickening was in fact an area of disease, but was not an enlarged node on clinical examination. The CT scan of the node had been relatively normal. The PET scan showed only a small area of uptake. This meant that there was some disease in the node, but it was not enough to enlarge the node. Given the small amount of disease present in 2016, one could conclude that there was no disease present in the node in 2014.

263. There was a difference between a tumour being aggressive and its growth rate. A tumour could be aggressive, meaning that it would invade other areas. Most faster growing tumours would tend to be aggressive. Growth was the balance between the growth or proliferation of cells and the dying off of cells in the tumour. The dying of cells is known as apoptosis. If the growth rate is bigger than the dying rate of the cells, the tumour will grow. Accordingly one does not just look at the mitotic rate alone. For example in skin cancer there was often a high mitotic rate, but there was also a high death rate of cells, so in general it was not a fast-growing cancer. The mitotic rate was just one factor to be looked at. It was not the dominant factor.

264. The Bloom Richardson scale was a combination of three scores. No one factor was more important than the other. One considers other factors as well when assessing the growth rate of the tumour. Even having done such an assessment, one cannot say for certain how a tumour will develop.

265. Prof. Price explained the purpose of histopathology. That department would examine a biopsy specimen under the microscope. The age of the patient would not affect what they saw under the microscope. In this case there was a fairly standard DCIS carcinoma, which would usually be a Grade 2 or 3. In reaching a prognosis, they had prognostic tools, into which they would put the variables and this would give an estimate of prognosis. That would it be used to decide future treatment. Age was one factor in the equation. Younger people did not tend to do so well.

266. Prof. Price explained that in looking at rates of tumour growth, age was the dominant factor. It was known clinically that the most dominant thing in relation to the tumour was the age of the patient. It was for this reason that in screening programmes age was the main factor determining how often people would be screened in general. In Ireland people in the age category 50 – 70 years would be screened every three years. The three-year interval is used because tumours tend to be slow-growing and therefore it was safe to screen at that interval. Over 70 years tumours would be very slow growing, so they did not routinely screen people over that age. In younger women, while it is rare to get breast cancer, it is known that tumours grow quicker in younger people. For this reason for younger women who are in the high risk categories, they could be screened every year, or perhaps even every six months. It was internationally accepted that in younger people tumours tend to grow faster.

267. Prof. Price explained that she did not look at age alone when determining the probable tumour doubling time. She also looked at information from the histopathology report from the biopsy; the fact that the plaintiff was oestrogen receptor positive and HER-2 negative; that she was Grade 2 (including her mitotic score); together with her individual factors post diagnosis.

268. Prof. Price stated that one would factor in the plaintiff's young age in 2016, and then go on to look at the clinical factors, such as the primary tumour growth. One also had to look at how the metastatic disease had behaved. This would involve comparing progress of the disease between scans. If, for example, one had a scan and there was nothing on the scan and two weeks later there was a big 3cm mass present, then obviously that had grown very fast. It is that time interval that gave you what is called the disease-free interval. So in a patient with metastatic disease, they are constantly looking for what time it takes to metastasise and that would give them a flavour of how fast the disease was growing. They would also look at the response that there has been to therapy.

269. In this case the plaintiff had had some response to therapy, although Prof. Morris had stated that the response to hormone treatment had been disappointing. This was a poor prognostic disease, but she had had some very good treatment, but in comparison with other patients who had had early treatment and whose prognosis would be that 80% of them would be alive without disease at 10 years; in this case it was very close to the date of diagnosis and a much smaller amount of time had elapsed. So taking all of those factors together, it was her opinion that the tumour was more likely to be not at the tremendously fast end, but probably on the reasonably fast end of the scale. It was not on the slow end of the scale.

270. So looking at the applicable range for tumour doubling time, if one looked at the Tilanus-Linthorst paper a volume doubling time of 23 days was applicable at age 30 years. The Peer *et al.* paper went up to 148 days, with a mean of 80 days. In the circumstances of this case, she thought that between 44 and 80 days for this tumour was about right. That was her best guide to the court.

Interestingly, she noted that Prof. Bundred had initially felt that 80 days was about right as well.

271. In relation to hormone levels, generally the higher level of oestrogen in younger women, would tend to increase growth rate. However it was usually people who were oestrogen receptor negative who were put into the fast tumour growth rate, but here the plaintiff was oestrogen receptor positive. Due to this fact, there was limited response to hormone therapy. It was not that effective. She has had good treatment, but the tumour was still progressing.

272. Prof Price was asked about the fact that the plaintiff had survived to the present time. She stated that for an average woman, if she was diagnosed with early-stage breast cancer, and had had the disease taken out, then even without further treatment, one would not expect her to have the disease 10 years later. However once a patient had metastatic disease, the average survival time was 24 months, but there can be variables within that. That just reflects the growth of the subclinical metastases that are likely to be there early on.

273. Once a person has got metastatic disease, there was data which suggested that with oestrogen receptor positive disease, the average survival was about 24 months. Now within that there was a huge range. At one extreme, you could get a patient who hadn't relapsed for 15 years. If they then developed bone metastases, you would know because of that long disease-free interval, that they were probably going to last about 10 years once you treat them. These people who have had metastatic disease, we know that GPs have seen them all the time. They are patients that have metastatic disease for years. That is one extreme. The other extreme are patients that get early metastases and whatever you do they will only survive for something in the region of six months to a year. In this case the plaintiff had had extremely good treatment with newly available drugs. These were giving better treatment. The fact that the plaintiff was still alive. was a testament to the treatment that she had received. However it does not tell them whether the tumour is fast or slow-growing. The fact that she had exceeded the 24 month survival period, was more a comment on the effect of treatment, than on the rate of growth of the tumour.

274. Prof Price was asked whether it was likely that the plaintiff would have been node positive in 2014. She stated that this meant whether the disease had passed from the breast and had settled in the lymph-node and grown there. She stated that she believed that the plaintiff was not node positive in 2014.

275. She was asked whether the fact that the node had remained occult in the period between 2014 and 2016, was relevant. It was put to the witness that Prof. Bundred had stated that one could not really read anything into that. Prof. Price stated that the strongest evidence for her was that nobody had felt the node on examination in 2016. As already noted, all of the imaging done at that time, suggested that there was only a tiny amount of disease there in 2016. So, unless this tumour had not grown in the two years and it was just sitting there doing nothing for two years, or growing extremely slowly, which all of the evidence would suggest was not the case, then on the balance of probability, Prof. Price thought that the nodes were not involved in 2014.

276. Prof Price went on to say that in oncology they would never say "never" and perhaps this was an extremely unusual tumour that hadn't grown in two years. However that was highly unlikely. It could be put at less than 0.1%. But the key issue was that at diagnosis, they knew that there was a 2cm node in the mediastinum, so logically one would have to say that that was there, so she had metastatic disease two years ago, so she was in the same position. The biology of it did not fit. But if that was the case, then if the lymph node was sub-cortical thickening in the axilla, the 2cm lymph-node in the mediastinum which was classified as metastatic disease, had to have been present. So it could be, but it was very unlikely.

277. It was put to the witness that Prof. Bundred had disagreed with that analysis. He had said that the disease could sit in the node for a substantial period of time and he explained that by referring to the difference between distant metastases and local or regional nodes. It was put to her that he was of the view that she was wrong, because she had failed to take account of that distinction. Prof Price stated that there were effectively two pathways by which the cancer could spread from the breast. Firstly, it could go down the lymphatics to various nodes in the body, or it could go down the bloodstream, where it would settle once it reached areas where the tumour liked to settle, such as in the bone, the liver, the brain and the lungs. That was a separate pathway to the lymphatics, where the cells would go down the lymphatic system into various nodes. One could hypothesise that there was a completely different growth rate between cells that land somewhere from the blood and cells that land via the lymphatic system. She thought that that was what Prof. Bundred must have been thinking of. So he may have concluded that the bone metastases may have come between 2014 and 2016 and grown very fast, but that did not explain the nodes in the plaintiff's chest and supraclavicular fossa. She could not see how one could say that the tumour would have gone to one lymph node and then magically would not have gone to others and then they would grow in a different way. That just didn't happen.

278. It was put to the witness that Prof. Bundred had said that the tumour could sit there for a period of time and she had not taken account of that. Prof Price disagreed, saying that one would have to postulate that the primary tumour and the node were extremely slow-growing and then suddenly it sat there and did not go into any other lymphatics, when that was the way that it would usually spread. Biologically it did not make any sense. The chance of it happening would be less than 0.01%.

279. Prof. Price stated that the Peer paper was commonly used in legal cases concerning breast cancer. It was the first paper to look at age and it referred to other papers, which had come to the same conclusions. They knew from screening which had been carried out, that there was a faster growth rate in younger people. It was necessary to look at two scans, so that one can compare the size of the tumour over time. The Peer paper was based on Scandinavian data where screening is done routinely from the age of 40 years.

280. The Tilanus-Linthorst data took it one step further, because they looked at high risk patients, they had gone right down to people aged 20, 30 and 40 years. Between the two papers one had the ranges of volume doubling times between 20 year olds and 50 year olds. A lot of the other papers did not give age-specific results. They instead do a mean doubling time and the average age of patients may be 60 years or similar ages, so obviously they are going to get a higher result. The two papers are important partly for the references they made in the back of them, but also in the details of what they were looking at. The Tilanus-Linthorst paper had specifically looked at the effect of the mitotic rate on this and it did not come out as a significant factor. They found that age dominated everything. There was no subsequent data which did not support the conclusions in that paper. Nobody had disputed the conclusions reached in Peer on tumour doubling time. These conclusions had influenced decisions made in relation to screening intervals.

281. It was put to the witness that Prof. Bundred had stated that while there were 236 patients assessed in the Peer paper, only 32 of those were under 50 and out of the entire cohort six could not be assessed, so there may be as few as 26 in the sample. He suggested that half of those under 50 years would be Grade 3. Prof. Price witness stated that the Peer paper did not record the grade. In the 70% of patients, who were around the menopausal or postmenopausal age, or were oestrogen receptor positive, there would be a difference between grades two and three, however the Peer data did not look at grade separately, it only looked at age. Prof. Price confirmed that it was still the data that was referred to by people like her when considering general screening programmes.

There was no data that had come out that did not support the Peer conclusions. In fact, the Tilanus-Linthorst data, which looked at the age group between 40 and 50 years and older, their measurements exactly mirrored the Peer conclusions. This data had been accepted and that was why they had adopted the screening intervals which are in use commonly in the UK and Ireland. Nobody was disputing this data.

282. Prof Price accepted that in about 10% of younger women their tumour could be Grade 1. However Tilanus-Linthorst did not find that grade was the dominant factor in the overall consideration. It was simply something that you put into the mix and would consider with age and other factors in considering whether it was likely to be at the faster end, the slower end, or of the middle of the range.

283. In relation to the Michaelson paper, it was not looking at standard volume doubling times. Usually this would be measured from a comparison of serial measurements taken over time. However what they did there was that they tried to work out what would be the growth rate if you only had one measurement. What they did was, that they got a dataset from the MD Anderson hospital of 800 patients, who had only had one scan and they looked at the timing of when they had intervals in age, et cetera, so in fact the methodology was one of looking at the pathology size when you screened patients, versus the number of patients that were diagnosed. It was a very complicated model. They assessed that against the volume doubling time and said that was what it was, but in fact the dataset that came out at that 130 days, was actually based on only 110 patients who were screened and detected with one measurement and the average age was 61. So it was looking at an older age group and by that methodology one can only get a median, that's the most commonly occurring doubling time rather than the average and you cannot get the range. Accordingly she did not think that that paper was terribly helpful. It was more useful to tell them how frequently in their hospitals they should undertake screening, that was all.

284. Prof. Price stated that in reaching her range for the correct tumour doubling time, she had had regard to the Tilanus-Linthorst paper, which suggested that because there was literally a range from age 50 years right down; if one did the intersect at 32/33 years you would expect something which could go down as low as a tumour doubling time of 23 days. However she had not taken the extreme lowest at 23 days, it could go up to 80 days. When one took into account all the factors that have been mentioned, she did not think it was likely to be at the extreme end, it was more likely to be in the range of 44/80 days. She was comfortable with that range because it was not moderately differentiated. That remained her opinion and nothing she had heard had led her to change that.

285. She confirmed that in reaching her opinion she had had regard to the histopathology report and to the 3+3+1 score, but had also looked at a number of other factors as outlined above.

286. It was put to her that Prof Bundred had stated that he did not think that anything less than 80 days was relevant. Prof Price stated that she did not know how he had reached that conclusion. He had not said what factors he looked at to reach such a conclusion. He had referred to the Tilanus-Linthorst paper in his first report and had come up with the same result as she had. The Tilanus-Linthorst paper contained important data, because it screened young women and also looked at whether they had the BRCA 1 gene. It did not matter if they had the BRCA 1 or BRCA 2 genes, but age was found to be relevant. This was important data. It showed that in young people, who were in the high risk category, they should be screened regularly. She considered that the conclusions in the Tilanus-Linthorst paper were still valid.

287. In relation to the Amelove paper, that dealt with the S – phase fraction, which was a measurement which provided some guide to the proliferative component. They concluded that there was a weak correlation with volume doubling time, but they had not done the multifactorial analysis as to whether this came out. It was simply one factor that may be important. What you would need, was to have a paper that showed you that mitotic rate was completely related to growth rate. There was no paper that did that, whereas age was absolutely dominant. So it was not determinative, but was just one factor that had to be taken into account.

288. In relation to tumour palpability, this depended on breast size, but in general, one would not be able to palpate a tumour which was less than 1cm/1.5cm. That was the accepted threshold. In the literature it was put at 1.5cm in premenopausal women because they had more nodularity in their breasts. Tumours were normally found in the upper quadrant of the breast. If they were in the nipple area, they could be more difficult to palpate.

289. Prof Price explained the methodology for back extrapolation of the size of a tumour at an earlier date. She said that it was simply the application of a formula, which was available online. She noted that Prof Bundred had stated that the formula for the volume of a sphere was volume equals $\frac{4}{3} \pi r^3$. This meant that once one had a sphere, to work out the volume of that sphere, it can be assessed from the diameter. Volume was $\frac{4}{3}$, that was a number, pi which was 3.1442, times the radius which was half the diameter cubed. So as long as one had the diameter one could assess the volume. Once one had the volume one had to try and find out what the tumour doubling time was, so as to back extrapolate the size of a tumour at an earlier date.

290. Volume doubling time was a standardisation, it was the time taken for the volume to double. If you have a volume which was, for example, 46.79 that can be entered in and if the time interval was 669 days, if it had an 80 day tumour doubling time that would mean it was 5.2 less in volume. You can work out what the volume would be and then get your volume and convert it back to a radius. She thought that that was probably what Prof Bundred had done. She used to do it in that manner. However it was a very difficult task and one needed a scientific calculator. It was much better to use a scientific calculator which was now available online, so the formula taken there had actually put the logarithmic value on it, so it actually does all of the assessment for you. She did not think that he had used that calculator because she had checked and triple checked the data in the formula and it gave the same result as she had reached. For this reason she thought that what Prof Bundred had done, was to do a small amount of rounding up, because he had done it sort of manually. She had checked the measurements against the published calculator and she had given the maths of how it can be worked out accurately, whereas all Prof Bundred had done was to give the method of how to work out one measurement. She could only assume that he had tried to do it manually to get it the other way.

291. Prof Price commented on Prof Bundred's letter and stated that she was of opinion that he had misunderstood the image that she had produced in appendix 2 of her report, which he referred to as an image of the node, but it was in fact an image of the breast. Furthermore mild cortical thickening did not mean that the node was enlarged. If one looked at what was presented in 2016, the node was not palpable and there was only mild cortical thickening; accordingly, she was of the opinion that it was unlikely that there was a palpable node present in 2014. Dr Redahan's note in 2016 clearly stated that there was no lymph-node palpable. Mr Allen's note also referred to the axilla examination being negative, meaning that the surgeon had not found anything on palpation of the axilla. The CT scan did not record anything that caused concern. The nodes appeared normal in that scan. The scan done at the Blackrock clinic stated that there was increased FDG uptake in a 1cm left axillary node. This meant that the node looked normal, but there may be something in it.

292. Prof Price noted that the scan from the Blackrock clinic had specifically referred to a 1cm node, so that would not have been palpable.

293. From the mammogram, one could back extrapolate using a tumour doubling time of 80 days giving a tumour of 0.6cm in 2014. If it was back extrapolated from the clinical examination in 2016, when it was thought to be 4cm, that would back extrapolate to 0.5cm in 2014.

294. In cross-examination, Prof Price accepted that sometimes a patient will be able to feel a lump, but the GP will not be able to do so. In this case as the GP was not able to palpate the lump in September 2014, she thought it was reasonable that she would reach the diagnosis that she had done, that it may have been a transient lump connected to the patient's long-standing eczema. She accepted that a node that was infected would tend to be tender, whereas a malignant node would tend to be hard.

295. It was put to her that the plaintiff had attended complaining of a non-tender lump under her left armpit, which had been present for three months. Prof Price stated that her understanding was that the plaintiff had felt something in her axilla, but the GP was unable to find anything on palpation, so it was reasonable to conclude either that it may have been connected to the eczema and had gone, or that there was nothing there at all. Prof Price stated that she was aware that the plaintiff had stated that she had had the node for the two years prior to 2016.

296. Prof Price confirmed that in her letter accompanying her medical report she had stated that by back extrapolation, she had estimated the size of the tumour at between 1 – 5mm in 2014. That had been based on a 4cm lump in 2016 on clinical examination, if that was back extrapolated using a tumour doubling time of 80 days, it gives you 5mm in 2014. If that was extra back extrapolated using 44 days, one gets 1mm in 2014. If one takes account of the evidence from the surgeon, that it grew within a month from 4cm to 5cm between August and September 2016, that would put it more at the 40/44 days for tumour doubling time, which would put it more at the 1mm size in 2014. Both sizes were impalpable, therefore both would mean it was node negative. Accordingly, she did not think it mattered which estimate of tumour doubling time was taken.

297. Prof Price stated that it was impossible to give an absolutely definitive size. It was appropriate to give a range. She thought that the range she had given to the court was fair. As she had said before, she did not think that the tumour was so fast that it was less than 1mm, nor did she think that it was so slow, that it was more than 5mm in 2014.

298. Prof Price explained the TNM score. T was the tumour size, N was the nodal status in terms of regional nodes and M was the metastatic status. They knew that in 2016 the T stage was a T3. It was 3cm node positive in the axilla and it was metastatic. So we have got the TNM stage. What she had done was to back extrapolate that to 2014. She stated that in relation to the primary tumour, the clinical measurements were T1 a, and the importance of that was that it gave doctors a sort of slightly lookup table as to what the management should be and what was the broadly likely outcome. So the whole structure of the argument was that as an expert, you had to work out what was the description of the tumour there and what it was earlier. There were also other factors, such as the oestrogen receptor status and grade, which were important. The grade will stay the same, because that is the inherent biology of the tumour, as opposed to a description of where it is. Other factors such as the oestrogen status and the HER-2 status were also important. However those could vary with metastatic disease. But in this case, the biopsies has shown that these had not changed. They both remained oestrogen positive and HER-2 negative.

299. Prof Price was asked further about what the TNM stage of the assessment comprised. She explained that the T stage dealt with the size of the tumour. She had set out the various sizes ranging from TX to T1 c at appendix 9 to her report. In this case the tumour was size dependent. So the size of the tumour at diagnosis in 2016 was important. In this case it was found to be T1 a, which meant that the tumour was more than 0.1cm but not more than 0.5cm. The N stage dealt with nodal spread, which looks at whether any of the regional or distant nodes are affected by the cancer. And lastly there is the metastatic spread, which has a classification of MO meaning that there is no sign of cancer spread, or M1 meaning that the cancer has spread to another part of the body.

300. In addition to the TNM analysis, one also looks at one's own clinical experience of the type of tumour involved. Some tumours are known to progress slowly, such as prostate cancer, whereas others are known to spread quickly, such as leukaemia. Then one looks at the available literature as set out in the various papers, to estimate what will be the likely tumour doubling time. One also takes account of tumour specific information in relation to the particular patient.

301. Clinical experience was critical to the evaluation. In this case, one could say that if in 2016 nobody had felt an axillary node and clinically there wasn't an enlarged node, then from clinical experience one knows that tumours do not tend to shrink on their own, so on the balance of probability in 2014, there was not a clinically palpable node, or a clinically enlarged node.

302. Prof Price accepted that clinical axillary assessment was somewhat unreliable in relation to predicting the presence of cancer in the nodes. She stated that the figures were, that if one had a clinically negative axilla node, a person still had a 30% chance that there would be some microscopic spread of the cancer. Equally, if a person had enlarged nodes, they still had a chance that the nodes were not involved. In this case, the node felt clinically negative and on the ultrasound examination, a very small area was revealed, which was biopsied and that showed that the cancer was present in the node. This highlighted the difficulties that there were in assessing the presence of cancer from a clinical axillary examination.

303. When a patient presents with breast cancer it is necessary to know the nodal status. Accordingly they would do an ultrasound and if they saw something such as mild cortical thickening, then a biopsy would be done. If nothing was revealed on ultrasound, a sentinel node biopsy would be done at the time that surgery was being carried out on the breast. Thus as part of the treatment of breast cancer, one had to know the nodal status. There were a number of ways that that could be done. If there was an enlarged node, you could put a needle directly into it. If an ultrasound was done and something was shown up, then a biopsy could be done.

304. Prof Price was questioned about her clinical experience in the treatment of cancer. She stated that she was a primary treating consultant dealing with cancer from 1989 to 2000. She primarily dealt with the areas of gastrointestinal cancer and breast cancer. It was common for specialists to specialise in two areas. From 2000 onwards her primary focus had been on research. Her particular speciality was PET imaging, in respect of which she was an acknowledged world expert. However she had worked in the Imperial College Healthcare Trust Hospital as part of the NHS up to 2015, when she had had to give that up because she was doing work directly for the government. She continues to work in private practice in Harley Street in London. During all those years, although she was not the primary treating oncologist, she did participate in frequent multidisciplinary team meetings, where she would advise generally in relation to patients' treatment, in particular whether they were suitable for radiotherapy.

305. She accepted that she had not had an NHS appointment since 2014/2015. However she reviews the breast cancer pathways for treatment that are implemented in the NHS. So she is operating at a senior level in research and management in relation to the treatment of breast cancer.

306. She has given evidence in relation to tumour doubling time in very many cases. In the area of growth rates of tumours, she felt

that her opinion was highly relevant to the court. There would be other areas of treatment, for example in the treatment of a melanoma, where she would defer to others. In relation to Prof Bundred, she stated that he was a very experienced cancer surgeon. However he would not have had experience in the treatment of metastatic disease elsewhere in the body. Surgeons would not be involved in the treatment of metastatic disease, that was her area. As a surgeon, he would not be authorised to prescribe chemotherapy for a patient, as that is not his area.

307. It was put to the witness that Prof Bundred was of the view that one should take the mammographic size rather than the clinical size, because it was known that clinicians may not be that accurate. Prof Price accepted that in terms of accuracy the mammogram was more accurate. However, Prof Price explained that she had looked at the range of measurements that were available from various sources in 2016. The worst case scenario was that it was 5cm, which would put the lump at 0.6cm in 2014. If one went from the size at clinical examination of 4cm, then it would have been between 0.1/0.5cm in 2014.

308. She did not agree with Prof Bundred that one would always operate from the mammographic size, rather than the size on clinical examination, because the measurements taken tell you something different. However in general she would agree that the mammogram was more likely to be accurate in relation to the underlying size of the tumour. So she was in broad agreement with Prof Bundred on this aspect.

309. In relation to the formula used for back extrapolation, Prof Price stated that the maths used was not terribly complicated. It was possible to use a calculator on a computer system. At a tumour doubling time of 80 days, Prof Bundred got 0.8cm for the size of the tumour in 2014. She thought that that was actually incorrect; he appeared to have used a tumour doubling time of 90 days. When she used the same formula on a tumour doubling time of 80 days, she got a result of 0.6cm for the size of the tumour in 2014.

310. Prof Price accepted that if one took a tumour doubling time of 100 days the size of the tumour in 2014 would have been 9.94mm. At 130 days it would have been 14.44mm. It was put to her that if one was reading from the mammographic size, and if one used a tumour doubling time in the range of 100/130 days, it would back extrapolate to a tumour measuring 1cm/1.5cm in 2014. Prof. Price agreed that that was so.

311. While Prof Bundred's back extrapolation formula was correct, if one used a tumour doubling time of 100/130 days, she did not agree that that was the correct tumour doubling time to use. She was of opinion that the correct tumour doubling time was in the region 44 – 80 days. She had relied on the papers by Peer and Tilanus-Linthorst in reaching her opinion.

312. Normally back extrapolation would be done from the pathological size of the tumour, which would be assessed after it had been excised. This was the gold standard. However that was not available in this case. In these circumstances it was appropriate to do a range of back extrapolation from the mammographic size, the size on clinical examination and the size as disclosed on ultrasound scan. She disagreed with Prof Bundred that one would only use the mammographic size. She thought that all three should be used.

313. Prof Price was asked, if one assumed a mammographic size of 5cm and a tumour doubling time of 100 days on 23 August 2016, what the likely size of the tumour would have been on 12 December 2014. She stated that on those figures the tumour would probably have been 11.94mm (1.2cm). Using a tumour doubling time of 135 days, the tumour would have measured 17.3mm in December, 2014.

314. Prof Price accepted that she had not referred to grade of tumour in her report, however she stated that it was one of the factors that she had taken into account. She had explained why she had not placed this tumour either at the very fast end, or at the very slow end of the scale for tumour growth. She stated that if she had not taken the fact that the tumour was Grade 2 into account, she would have been at the much lower end of the scale in relation to tumour doubling time, possibly as low as 25 days having regard to the plaintiff's age. However given that she had a Grade 2 tumour, she had opted for a longer tumour doubling time.

315. In relation to the histopathology report, which stated that the tumour was "at least Grade 2". The mitotic score component was arrived at by counting the number of mitoses visible under the microscope. If one only had a small sample, the number of mitoses may be small. So when the histopathologist said that the tumour was "at least grade 2", he or she was indicating that the grade may go up. It could not go lower because it had the lowest score. So it could be a grade 3 tumour, or very close to it. The exact mitotic rate ascertained, could be erroneous given the size of the sample, because if there were more than seven mitoses, it would obtain a mitotic score of 2, which would have pushed it into a grade 3 tumour.

316. For the purpose of reaching her opinion, she had assumed that it was a grade 2 tumour. However, even if it was assumed to be a grade 3 tumour, that would not have changed her opinion. Accordingly the mitotic rate would probably not have changed her opinion, unless it was increased to a very large number. The mitotic score was a factor which had to be taken into account along with other factors. She had taken it into account, or else she would have arrived at a faster tumour doubling time.

317. Prof Price stated that she could not see any evidence or logic as to why Prof. Bundred had changed his opinion based on the mitotic score of one. If anything his second report had strengthened her opinion. The additional papers referred to therein, were on older women, so they did not appear to be very helpful.

318. Prof Price stated that she was not at all clear why Prof Bundred had opted for a tumour doubling time of 130 days. She did not agree that it was appropriate to base that on the Michaelson paper, because that was based on women who were 61 years of age, so she did not think that it could support a tumour doubling time of 130 days in this case. Furthermore that paper dealt with actually less patients than in the Peer paper. It took account of older patients and did not take account of grade. She could not see the evidence on which he had based his opinion that a tumour doubling time of 100 days could be relevant, or why he had opted for a tumour doubling time of 130 days. She could not see how he had arrived at those conclusions. A tumour doubling time in the range 100/130 days did not fit with the data in the Peer paper or the other papers, so she did not think that it was the correct tumour doubling time to adopt in this case.

319. In her report at paragraph 6.2 she had factored in the grade of the tumour, the conclusions in the Peer and Tilanus-Linthorst papers and her clinical experience. She came to the opinion that her estimate of the appropriate tumour doubling time meant that the tumour would have been between 1.2mm and 6.6mm on mammographic size, or clinically it would have been between 1mm and 5mm in 2014.

320. She pointed out that at paragraph 6.2 of her report she had stated "Therefore while the tumour would have been stage TI a, in September 2014, on the balance of probability it would not have been detectable on clinical examination and therefore likely no referral to the breast clinic made. Had a referral been made, the tumour may have been detected had a mammogram been performed".

321. It was put to the witness that Prof Bundred had considered the grade of tumour, the mitotic rate and the progression of the disease in the particular patient. She agreed that progression of the disease in a patient was an important factor. Once you had metastatic disease and growth rate, you then proceeded to look at what was actually happening in the patient in front of you.

322. Prof Price stated that in reaching her opinion because of the patient's age and in light of her clinical experience and in light of the fact that she had a grade 2 tumour, which was oestrogen receptor positive and HER-2 negative, and based on the conclusions in the Peer and Tilanus-Linthorst papers, she had ended with a likely range of tumour doubling time of 44 – 80 days. The essential factors were age, clinical experience, the literature and the specific experience of this tumour in the patient. She accepted that she could have been more detailed in her report in relation to the factors which she had taken into account when assessing tumour doubling time. She stated that she had taken account of clinical experience and the grade of tumour.

323. Prof Price accepted that it was appropriate to look at how tumours in similar cases had progressed in other patients and how they had responded to treatment. Doctors look at evidence-based studies of the general population to understand the progression of cancers generally.

324. In relation to the number of patients that formed part of a particular study, while she agreed in general that the larger the number of patients looked at, the greater the level of data would be; however just because there may be a smaller number looked at, might not be a particular disadvantage, depending on what was being looked for in the study.

325. The Peer paper did not set out to find if there was a correlation between grade of tumour and growth rate. It looked at people who had been screened on at least two occasions. The authors were looking at growth rates so as to know how often people should be screened. They had excluded some patients from the study and had been left with 236 remaining cancers. However these were not interval cancers, which is a cancer which arises between scheduled screenings. She did not understand how Prof. Bundred had come to that conclusion. The study was not confined to the study of interval cancers. His conclusions were based on patients who had had at least two mammographic screenings. If it was picked up on the second occasion of screening and then found to have existed at the time of the first screening, then it was not an interval cancer.

326. Table 2 in that paper showed that there were 32 patients in the range 41 years to 50 years. As six patients were taken out of the overall equation, one could have been looking at between 26 – 30 patients. She accepted that that was a small number. The Tilanus-Linthorst paper had looked at approximately 43 patients. It showed that on the data available in younger patients, there was a faster tumour doubling time. They had based national screening programmes on these conclusions. Therefore more frequent screening was put in place for younger people who are at risk of developing breast cancer. In the group of younger women who are at risk, they would scan on a yearly basis and in the very young, who are in the high risk category, they could be scanned as often as every six months.

327. Prof Price stated that the Peer paper and the Tilanus-Linthorst paper clearly established that the growth rate of a tumour was faster in younger people. As the Tilanus-Linthorst paper concluded for every decade there was a 10% change in the growth rate. Accordingly those in their 30s would be slower than those in their 20s, but it was only a marginal change. The essential point was that in younger people the tumour tended to grow faster. In those aged 50 to 70 years tumours tend to grow at a slower rate and in those over 70 it was slower again. That broad classification was not going to change. It had been well established over time.

328. Table 3 in the Peer paper showed that for the 40 – 50 age group, the range of tumour doubling time was from 44 – 147 days and the mean was 80 days. It was important to note that that data did not refer to patients who were in the 30 year old group. That was an important factor which explained why she had not gone for 147 days and why she did not think that 100/130 days was appropriate, because that would be slower than the average for the 41 to 50 year old age group. It was illogical to suggest that people in the 30 year old age group would be slower than the average in the 40 to 50 year old age group.

329. Prof Price explained that the figures 44 – 147 in table 3 referred to the confidence interval. It was not the range of applicable tumour doubling times to the patients in the sample. It was the confidence of what it was most likely to be. A computer would provide a statistical test. So there was not any patient who actually got 44 days, nor was there a patient that got 80, it was saying that 80 was the average and those were the confidence intervals, so that in that group of patients being 40 to 50-year-olds, it was likely to be in that range. However, on further questioning Prof Price accepted that there would have been some patients at around the 44 or 45 day mark and there would be some higher than the 147 mark and there would be some around the middle. She accepted that even in that small survey there was variability. It was put to her that this was a very large variability. Prof Price stated that the real benefit was in the comparison with the other age groups. In the 50 to 70 year age group, the mean was 157 days. So they would be in a different range altogether. The essential point was that the bulk of the people in the lower age group had a much shorter tumour doubling time than those in the higher age bracket.

330. There was only some small overlap between the lower section in the older age group and the upper section of the younger age group. Prof Price explained that the confidence intervals would be different between the two age groups due to the fact that there was no routine screening in the under 50s, whereas there was routine screening amongst the people aged 50 – 70 years and there was again no routine screening amongst those above 70 years. If one did a statistical test the confidence intervals are wider if you have less patients, but what was clearly shown in table 3 was that the mean tumour doubling times for the relevant age brackets of 80 days, 157 days and 188 days. That was the significant thing to take from table 3. There was a big difference in terms of age group and the question posed in the paper was, whether there was a difference between age and growth rate and the answer was clearly that there was a big difference, with three different mean tumour doubling times for each age group.

331. Counsel put it to the witness that in table 4, which contained a review of findings in other literature, only one paper dealt with those with a mean age of less than 45 years and that was the Kuroishi paper which showed a mean doubling time of 174 days. Prof Price pointed out that in commenting on the other studies the Peer paper had concluded: "The current study confirmed the positive correlation between age and tumour volume doubling time that was demonstrated in other studies." That was their final conclusion in the matter and they also found that other studies had reached similar conclusions. It was not a controversial proposition that tumour doubling time was age-dependent.

332. It was put to the witness that Prof Bundred was of the view that the reason why younger patients tended to have a faster growing cancer, was that they were more likely to have a rapid growing cancer such as grade 3 tumours. Prof Price stated that Prof Bundred had not produced any evidence for that assertion and the evidence from the Tilanus-Linthorst paper was completely the opposite. They had actually studied patients closely and looked at the mitotic rate and grade of tumour and it fell out of the equation when age was factored in. Age trumped everything.

333. Prof Price stated that the literature clearly stated that younger patients had faster growing tumours. They may like to have a

table similar to table 3 that instead of age down the left side would have had a column for tumours that were G2 and G3 or a mitosis score of one, two or three and if they had such a table showing that there was a difference in tumour doubling time with such tumours, that would be fine. However there was no literature of that sort in existence. Prof Bundred had not found any literature and all the literature that did exist suggested that there wasn't a relationship along those lines.

334. Prof Price accepted that if a person was in their 20s they were more likely to have a grade 3 tumour. If they were in their 40s there was a 50-50 chance that they would have a grade 2 or grade 3 tumour. The Tilanus-Linthorst paper confirmed that. Patients in their 20s with breast cancer were more likely to have a higher grade tumour. Those in their early 30s were also more likely to have a higher grade, whereas those in their late 30s and early 40s would have nearer the 50-50 mark. She accepted that it was probably true that for those in their early 30s they were likely to have a higher grade tumour.

335. In relation to the Tilanus-Linthorst paper of 2005, as this was a study of younger patients, it was very important. In the UK people were not screened routinely below the age of 50 years unless there are in the high risk category. Over 50 years they were screened every three years. Patients with the BRCA 1 and BRCA 2 genes were at a higher risk of developing breast cancer. The patients studied in the Tilanus-Linthorst paper had these genes, or had a high family history of breast cancer. Accordingly they were at higher risk of developing cancer and therefore were screened at an earlier age. Prof Price accepted that there was no evidence that the plaintiff had either of these genes, or had a significant family history of breast cancer, however the Tilanus-Linthorst paper was still relevant. The reason why the young people in the Tilanus-Linthorst paper were screened was because they were at a higher risk of developing cancer, but those that did go on to develop cancer would have a growth rate that was the same for all people in that age group. Accordingly the conclusions in the paper were relevant to patients and the general population in this age group. The paper clearly concludes that growth rate in young people was faster.

336. It was put to the witness that Prof Bundred was of the view that this paper was not relevant to the plaintiff, as she had no relevant family history of breast cancer. Prof Price disagreed with that view. If one considered the results in the paper it was stated that there was no difference between those with the BRCA genes and the other patients in that age group. In light of that conclusion he may have to reconsider his opinion.

337. Prof Price stated that the important conclusion to draw from the paper and from the results of the study was the conclusion that once age was present, the mitotic rate or the grade of tumour fell out in terms of importance; the important thing was age. That was consistent with every other study produced to date. Nothing had been produced to say that grade affected those results.

338. Prof Price pointed out that at P. 1613 it stated as follows "*The tumour characteristics grade and mitotic count differed between the two risk groups. At univariate analysis, mitotic count correlated with DT ($P = 0.03$) while grade did not ($P = 0.3$). When mitotic count and grade were entered into the multivariate model the results remained essentially unchanged with P value for age, grade and mitotic count P equals 0.015, P equals 0.8 and P equals 0.4 respectively*". Prof Price stated that she had seen no study that said that there was an independent variable of M1 or grade.

339. Prof Price stated that in the Tilanus-Linthorst paper the patients were selected because they had a susceptibility to developing cancer. It was due to that susceptibility that they were chosen for screening. After that there was a correlation with age going right down and the mitotic rate and the grade were not relevant. The grade had no correlation and the mitotic rate was not terribly important. It was the age that dictated what the doubling time was. That was what the paper clearly showed. She referred in particular to the graph shown in figure 3, which went from 66 years down to 25 years. It was that correlation that was important, which is where they got the main result of this paper that every 10 years there was a 10% slowing in growth rate. The important thing about this paper was that it agreed with the data in the Peer paper, which had looked at the 41 to 60 year old age group and reached the same conclusions. So the Peer data was not selective, it fell exactly on the curve as shown in the graph in figure 3 in the Tilanus-Linthorst paper.

340. This was clearly stated in the conclusion section of the paper where it stated at P. 1617 "In conclusion, age at detection is the main indicator for growth rates of hereditary and familial breast cancers. If screening may prove indicated from a certain age on, the woman's age and not the risk group should determine the screening interval. A high-sensitivity biannual test may be appropriate before age 40 years."

341. Prof Price did not agree that the results in that paper were confined to a conclusion that age was the main indicator of growth rates in cases of hereditary and familial breast cancer only. The essential conclusion was that age was a relevant factor in treating and screening populations. This type of data was used now to make sure that the right screening interval was used. Nobody was saying that if a person did not have a family history they need not worry and need not be screened so often at that age group. She accepted that people under 30 were not routinely screened because they were not at a high risk of developing cancer. However the risk of developing cancer was unrelated to the growth rate, if it should develop. In that scenario age was the important factor as had been shown in the literature.

342. In relation to the Michaelson paper, Prof Price indicated that the author had gone through a very complex mathematical model, which was based on four types of population; women who are diagnosed at screening, interval ones, and prevalent screen and a recurrence rate and it put all those together to get a complex model to work out whether, if one finds a pathological size at screening and then you put in the numbers of patients, you come up with a broad measure of tumour doubling time. That depended on a number of different variables. However the group in which the figure of 130 days was based, was 111 patients with a mean age of 61. It was not based on the numbers under 50 years of age. That was a completely different group of patients, it was quite misleading.

343. Basically they had got the women who had come in at screening and said the number of women screened when we get the pathological size and that is the number of tumours versus the population and from this they got a growth rate. It was a very complicated model. There were a lot of assumptions. But they had validated it by saying that it was about the same as most of the volume doubling times and that was satisfactory. They excluded a few young patients. So it was a very different thing and for that reason she could not understand why Prof Bundred felt that that was the most relevant paper because it was 61 year old patients and there was only on 111 of them and it was a median that was given, there was not a range.

344. In fact what Michaelson did show in the paper was that the interval cancers occurred in the younger age group. There was no surprise there, they knew that. In his earlier paper he had a whole list of interval cancers and they were in the younger age group. That was consistent with other literature. Interval cancers were most likely to be the faster growing ones, which is why he got them in the younger age group. In summary she thought that it was a methodology paper which was kind of skewed and one could not get as much data out of it as one would wish.

345. Prof Price stated that she was aware of the Michaelson paper when doing her report. She had not relied on it for the reasons

outlined. She was surprised that Prof Bundred had relied on it. She would be interested to know why he had done so. She thought that he may not have looked at the previous paper on which it was based, because initially he had said that he had looked at it because there were more patients, but that was not true. And then he went on to say that they found the interval cancers in the younger patients and that was nothing to do with grade. So she was not sure why he was using the paper.

346. It was put to the witness that this was because Michaelson had used a different methodology. She said not only did it use a different methodology; there was a non-opaque group of patients and when one got into it, it did not give you a range, it was not based on serial mammography. It was based on a mathematical model of the prevalence of tumours, which may be very specific for the hospital in question and they had said that in the papers.

347. Counsel put it to the witness that in the Arnelove paper it stated as follows "Tumours that are growing rapidly on mammography have higher specific values than the more slowly growing ones, which indicates a correlation between tumour growth rate and cellular proliferation." Prof Price explained the meaning of S – phase fraction and stated that it was not the mitotic rate that has been looked at, it was the synthases rate. Then one looked at the peaks and would measure it. So it was one measure it was not quite the M1 measure, but it was broadly in that category. This was something that she had factored in when considering the applicable tumour doubling time. She had not factored in the S-phase fraction, because they do not measure that any more, but it was the M1 score which showed that the tumour was moderately differentiated. It had been factored in in her analysis and that is why the tumour doubling time was not at the lowest applicable end for young patients.

348. Prof Price agreed that the history of this particular disease in this particular patient was a very important factor. She had been diagnosed in August 2016 and broadly speaking of patients who had metastatic disease, their general survival rate from diagnosis would be 24 months. Prof Price accepted that the plaintiff had survived longer. However it was important to note that she had had a large amount of good treatment with very modern drugs and she had had a small volume of metastatic disease at diagnosis. She thought that the difference between the anticipated survival time of 24 months and the current survival rate of circa 28 months was due to a treatment effect. The original survival expectancy of 24 months had been based on the availability of older medications. What one was seeing in this case was a treatment effect. It had nothing to do with the growth rate of the tumour.

349. She accepted that Prof Morris had said that the plaintiff's tumour had not responded well to treatment. However she had had some response to hormone treatment, but as she was ER positive, they would have hoped for a better response to such treatment.

350. In relation to the axillary node, it was known that in 2016 there was cancer in other nodes. It was not in every single axilla node, but was in some of them and had spread to other nodes elsewhere in the body. They could only see one node on ultrasound, it was possible that they could find more if a surgeon had gone into the area. It was not known how many nodes were involved.

351. Prof Price accepted that tumour size and lymphovascular invasion were often predictors of axillary metastases. They were indicative of how likely one was to have the nodes involved in the axilla. That was contained in the Reyal paper. Her opinion was that if the tumour was only 1 – 5mm in 2014, she thought that it had probably not metastasised at that time, because statistically it was less likely to. While it was true that the larger the tumour the more it was in the lymphovascular space and the more likely that it was going to send out metastases through the armpit and elsewhere, but the prognosis was more dependent on nodal status, than the size of the tumour. It was put to the witness that in the Tilanus-Linthorst paper it said *"Although breast cancer cells may disseminate early, tumour size and lymph-node status remain strong prognostic factors for survival"*. The witness agreed with that statement.

352. It was put to the witness that in her report she had put forward the proposition that had there been axillary node involvement in 2014, in her view the cancer was already metastatic breast cancer in the distant metastases and the prognosis ultimately would have been the same. The witness agreed stating that the mediastinal node was 2 cm, the supraclavicular fossa node was 1.5cm. If they were present there, that by definition was metastatic disease. That was in 2016, when the node in the axilla was only 1cm.

353. It was put to the witness that she was of the view that in 2014, if this was a slow-growing tumour as Prof Bundred suggested, that there was already distant metastatic disease present in 2014. The witness agreed. However it was not correct to say that a person with distant metastatic disease in 2014, was likely with treatment to have a life span of two years. This was because it was subclinical at that stage and one would have the lead time before it became discoverable. Then there was the question as to whether treatment is different if given earlier. Treatment will hold it for a period. If one had a smaller volume of metastatic disease and one received the treatment, it would hold the disease until the tumour became resistant to it. So she had concluded that had treatment been started two years earlier for metastatic disease, ultimately the outcome would be the same. She accepted that normally people who did not get any treatment at all, would have a worse outcome than people who did have treatment. It was put to her that as the plaintiff had not had any treatment for two years after 2014, that would surely worsen her outcome. Prof. Price stated that she had received treatment later on. Usually one could say that patients who do not receive treatment, versus those who do receive treatment, fare worse; however starting treatment earlier does not necessarily mean a worse or better outcome.

354. It was put to the witness that the Richards paper suggested that a delay in diagnosis can affect outcome. Prof Price stated that that paper was about diagnosis of early breast cancer itself. It was a population-based study, it was not done on an individual basis. He was talking about the primary disease and not metastatic disease.

355. It was put to the witness that the fact that the plaintiff was alive four years after August 2014 and coming into the fifth year was something that the court could take into account when looking back as to whether she had metastatic disease. Prof Price did not agree. She stated that usually metastases when they occur had been present for 2 to 3 years. That meant that those metastases would have been there earlier. She had felt that it was earlier, as it was a faster growth rate, which is why she thought that there was just a small window of opportunity when it wasn't metastatic, but if it was left much longer it would become metastatic, because otherwise the time interval was very short. Two years was very very short. In her view the small window of opportunity was probably from September 2014 to about January/February 2015. After that it would already have metastasised because it would have been big enough. With a very slow growing tumour one would have a long disease-free interval, with a faster growing tumour the disease-free interval was much smaller. She felt that because there was evidence of fast growth, on balance she felt that this was not a very nice cancer and that had it been left for any long period, it would have already gone to other parts of the body and the outcome would have been the same. One could not get away from the fact that this was not a good cancer.

356. Finally, it was put to the witness that Prof Bundred had stated that the longer a tumour sits in the breast untreated, the more likely it was to spread to the lymph nodes and eventually when it had sat around long enough, it gives out emboli into the bloodstream and it grows and opens up more blood vessels to be able to spread. Eventually some of these cells that are leaving the tumour can survive in another organ and it develops metastases. It's the length of time that it was sitting there that leads to metastasis. Prof Price stated that she would disagree with Prof Bundred when he said "It eventually goes to the lymph-node and

eventually into the bloodstream". It was thought that biologically it did both at the same time, which is why the nodal status is a predictor for prognosis in metastatic disease. It was not an incremental thing. It was not a question of staying in the nodes and then at a later time moving on. There were two different pathways. One predicts for the other, but it wasn't one that causes the other, so she disagreed with him on that aspect. The tumour could spread through the lymphatic system and through the bloodstream, but it didn't go from the lymphatic system to the blood system. There were separate pathways.

IV.IV Evidence of Professor Eamon Leen

357. Professor Eamon Leen is a Consultant Histopathologist at Connolly Hospital, Blanchardstown, and an Associate Clinical Professor of Pathology at the Royal College of Surgeons in Ireland. He received his primary degree from Trinity College Dublin in 1985, and has been working at consultancy level since 1996.

358. In the present case, he reviewed several slides processed at Beaumont Hospital of the plaintiff's biopsy of the left breast and left axilla. He was asked to assess the biological aggressiveness of the tumour, for which he prepared a report, dated 28th January, 2019, based on what he saw on the slides, as well as taking into account the reports of Dr. Marie Staunton.

359. Prof. Leen commented that the sampling provided was quite limited, as no mastectomy was performed, meaning that it was difficult to fully analyse the tumour. He was also critical of the limited number of core samples available. He stated that only two core samples were less representative of the tumour. He did concede, however, that the core samples taken were good.

360. He commented that, with regards to the Bloom-Richardson scale, the score of 3+3+1 for Tubule Formation, Nuclear Pleomorphism and Mitotic Count respectively, was an unusual spread. He stated that you tend to get 3+3+2 or 2+2+1. He further noted that the Mitotic Count in the tumour was quite low, and this may have been due to delayed fixation in the process of preparing the slides for examination by the laboratory technicians in Beaumont Hospital. However he accepted Dr. Staunton's assertion that there was no delay in fixation during the laboratory process in the hospital. He accepted that that assertion could be discounted.

361. In a situation where the Bloom-Richardson score was unusual, Prof. Leen asserted that a Ki 67 estimate would be desirable. It was not available in this situation and he did not criticize Dr. Staunton for that.

362. Prof. Leen commented that the strong oestrogen and progesterone receptor positivity, and the negative HER-2 status, all provided information about how the tumour was likely to behave.

363. Prof. Leen estimated in his report that the growth rate for the plaintiff's tumour would be at the upper end of the scale.

364. Regarding the axilla lymph nodes, Prof. Leen referred to them as being "shotty" and "firm and non tender". He confirmed that if a person had a skin condition, the node may react, and this may be the cause of it inflaming. He was of the opinion that if such a tumour was indeed node positive in 2014, then given the particular factors of this situation, it was unlikely that it would have remained occult for two years. He would have expected the node to get bigger if it was in fact metastatic. He was therefore of the opinion that the lymphadenopathy in the left axilla, which was described by the plaintiff in 2014, was highly unlikely to have been associated with the "probably small" primary breast carcinoma, which would have been present in the breast at that time.

365. During cross-examination it was put to Prof. Leen that when grading tumours, the histopathological analysis was more important than the age of a patient. He disagreed with this proposition, and stated that many text books regarded age as an independent prognostic factor.

366. Prof. Leen agreed with Dr. Staunton that the cancer was "at least" Grade 2. There was a consensus to this phrasing between them, as it was pending the resection of the tumour. It was put to him that the grade can only increase. He agreed with this and said that the grade never goes down.

V. The Law

367. The legal principles which are applicable when a court is considering whether there was a breach of duty by a medical practitioner are well known. They were set out by the Supreme Court in *Dunne (An Infant) v The National Maternity Hospital* [1989] IR 91. Of relevance in this case, are the first two principles which were set out in the judgement of Finlay CJ at P. 109:

"1. The true test for establishing negligence in diagnosis or treatment on the part of a medical practitioner is whether he has been proved to be guilty of such failure as no medical practitioner of equal specialist or general status and skill would be guilty of if acting with ordinary care.

2. If the allegation of negligence against a medical practitioner is based on proof that he deviated from a general and approved practice, that will not establish negligence unless it is also proved that the course he did take was one which no medical practitioner of like specialisation and skill would have followed had he been taking the ordinary care required from a person of his qualifications."

368. In *Collins v Mid-Western Health Board* [2000] IR 154, Baron J set out the principles that are applicable when one is considering whether there was a breach of duty by a general practitioner. In the course of his judgement, he set out the obligations which are on a general practitioner when acting with reasonable care, as follows: he must listen carefully to what he is told by the patient; he must ask questions of the patient in relation to what he has told him; he must ask questions on other relevant matters that are not mentioned by the patient; he must listen carefully to any information given by any family member of the patient, either at the consultation or when making the appointment; if appropriate, he must do a thorough clinical examination and while he may not be expected to be in a position to make a correct diagnosis, he is expected to be in a position to know when his patient should be referred to a specialist.

369. Later in his judgement, Baron J set out the test which the court must apply when considering whether the GP had been negligent. It was put in the following terms at P. 162:

"The test of the obligation of the general practitioner is whether a reasonably prudent general practitioner exercising ordinary care would have acted as he did in the circumstances. The reality of the test is to enquire whether or not the general practitioner acted reasonably in the circumstances as known to him."

370. Baron J also cautioned against the danger of having regard to subsequent adverse events, when considering the reasonableness of the conduct of the GP, when he or she saw the patient at some earlier date. He stated as follows at P164:

"In this type of case, hindsight is a problem. At the hearing, it was common case that the deceased had suffered serious trauma to the brain on 20 February, 1991. It is all too easy to assume therefore that the doctor is negligent because he fails to diagnose it. That is not the test. The questions to be asked are, did the doctor do all that could reasonably be expected of a reasonably prudent general practitioner exercising ordinary care and, if not, would what he should have done have led to a correct diagnosis either by him or by a specialist to whom he would have been referred."

371. It seems to me that the principles set out in these two cases, are the correct legal principles to apply in this case.

VI. Conclusions on the Technical Issue

372. On 12th November, 2018, the plaintiff's expert, Prof. Bundred furnished a report in which he stated that in women who were younger, there was an increased speed of tumour growth, he thought that 80 days was the correct tumour doubling time for the plaintiff. Applying that doubling time to the plaintiff's tumour which was 5cm at diagnosis, meant that her tumour would have been 0.8cm in size in 2014. In coming to those conclusions, he referred to the papers written by Peer *et al* in 1993 and by Tilanus-Linthorst in 2005.

373. On 17th December, 2018, the defendant's expert, Prof. Price, furnished a report, in which she also relied on the papers by Peer *et al* and by Tilanus-Linthorst. She accepted that in young women, the growth rate, according to the Peer data, was in the region of an 80 day volume doubling time. However, in women under 35, that could be faster. For that reason, she had assumed a growth rate of between 44 and 80 days. She noted that the plaintiff's tumour had been measured on mammogram in 2016 at 5cm, which would have meant that the plaintiff's tumour in 2014 measured between 0.12cm and 0.66cm, depending on which actual tumour doubling time was chosen within the range given.

374. On 9th January, 2019, Prof. Bundred, wrote to the plaintiff's solicitor in relation to various matters which he considered needed further investigation in light of Prof. Price's report. His main area of concern was in relation to Prof. Price's comments in relation to the size of the lymph node demonstrated on ultrasound scan in 2016. In relation to the size of the tumour in the breast, he noted as follows: *"With regards to the size, I calculated that the tumour would have originally been 8cm (should read 0.8cm), which is little different to Prof. Price's calculation of 0.6cm."*

375. On 16th January, 2019, Prof. Bundred issued a second report. In that report, he came to a different conclusion in relation to the appropriate tumour doubling time. In essence, he stated that having reviewed the histopathology report of Dr. Staunton dated 23rd August, 2016, he had come to the view that the grade of tumour, being Grade 2, and the mitotic score of 1, as set out in that report were significant factors, which he had missed when giving his original opinion. He stated that these factors indicated that the plaintiff had a very slow growing tumour. He revised his opinion to give a new range for tumour doubling time of between 100 – 130 days, which based on a tumour size of 5cm as shown on the mammogram in 2016, would have back extrapolated to a tumour size of 1cm – 1.5cm in 2014. In the course of his evidence, when asked at which point on the scale he would estimate the correct tumour doubling time to be located, he opted for the figure of 130 days.

376. Thus, it can be seen that while the two experts were initially quite close in the conclusions that they had reached in relation to the appropriate tumour doubling time, Prof. Bundred had changed his opinion significantly to arrive at a new tumour doubling time, thereby giving rise to a revised opinion in relation to the probable size of the tumour in 2014, being somewhat larger than originally estimated by him. In cross examination, he was questioned about this change of opinion. He said that when he had looked at Prof. Price's report and had seen that she had back extrapolated to a tumour size of 0.1cm – 0.6cm in 2014, based on a tumour doubling time of 44 – 80 days, he went back to the records to check his calculations. He said that in doing that, he realised that he had missed the significance of the histopathology report which put the tumour grade at Grade 2 and had also missed the significance of the overall scoring of 3+3+1, meaning that the plaintiff had a mitotic count of 1. He stated that the grade of tumour and mitotic score were significant factors which he had missed when preparing his first report.

377. In considering Prof. Bundred's explanation as to why he had felt the need to revisit his calculations, it is hard to understand exactly why he would have had cause to revisit his conclusions in the light of Prof. Price's report. Her conclusions had been broadly in agreement with the conclusions in his first report. His initial reaction to her report, had explicitly noted that they had reached broadly similar conclusions in relation to tumour size. That was set out clearly in his letter of 9th January, 2019. Thus, it is difficult to understand why it was that he decided to revisit his conclusions in the light of that report. Clearly, he had not any such intention when he wrote to the plaintiff's solicitor. It is possible that his revisiting of the conclusions in his first report may have arisen as a result of a subsequent telephone conversation which he may have had with the plaintiff's solicitor, as he had suggested a telephone consultation with her at the end of his letter.

378. In the course of cross examination, Prof. Bundred was questioned as to whether he had realised that his letter would have to be disclosed by the plaintiff's solicitor to the defendant's solicitor under the rules relating to disclosure in Irish law. He said that he was aware that his letter would be disclosed to the other side. It was put to him that the content and style of the letter were not of the type that would normally be in a document intended for disclosure to the other side by way of an addendum to a report, or a new report. In particular, it was pointed out that in the first paragraph of the letter, he dealt with travel details and his availability for the hearing. It was further put to him that the tone and content of the letter was more in the nature of a private discussion between an expert witness and his instructing solicitor, rather than a document which was intended to be furnished to the other side as part of the documents in the case. Prof. Bundred stated that he was aware that his letter would be disclosed to the defendant's legal team. However, I note that while Prof. Bundred has given evidence on numerous occasions before, this was the first occasion on which he had been called to give evidence in the Irish courts. There is considerable strength in the point made by senior counsel for the defendant that this does not appear to be the type of letter that would normally be furnished by an expert, if he had intended it to be furnished to the opposing side. However, it does not seem to me to be necessary to resolve this issue. The important thing to note is that at the time of writing that letter, Prof. Bundred was satisfied that the conclusion reached in his first report was *"little different"* to that reached by the defendant's expert.

379. Prof. Bundred's explanation that he came to change his initial opinion because he had missed the significance of the histopathology report and in particular its conclusions that the plaintiff had a Grade 2 tumour and had a mitotic score of 1, is a little difficult to understand. Prof. Bundred is an expert witness with vast experience in the treatment of cancer. He was consulted, not as a liability witness, but as an expert to give an opinion on a discrete technical question; being the probable size of the plaintiff's breast tumour in 2014. That involved calculating the growth rate of the tumour, so as to give an estimate of the appropriate tumour doubling size. Using that, and extrapolating back from the size of the tumour at diagnosis, one could estimate the possible size of the tumour approximately two years earlier, when the plaintiff had consulted with the defendant.

380. When preparing his first report, Prof. Bundred had had the histopathology report prepared by Dr. Staunton before him. Dr. Staunton stated that the report issued by her was in the same format as that used in hospitals in the UK. If grade of tumour and

mitotic score are so central to the calculation of tumour doubling time, it is difficult to understand how Prof. Bundred could have missed such important details when issuing his first report. However, the court must not lose sight of the fact that we are all human and as such we can make mistakes. As Prof. Bundred is an expert witness, whose primary duty is to the court, I accept his explanation, that he had missed these details on his first reading of the papers.

381. Turning to the central issue, which is the conflict between Prof. Bundred and Prof. Price as to the correct tumour doubling time to adopt in this case, there are a number of factors that must be looked at. Firstly, in relation to the relevant literature, it is significant that initially both Prof. Bundred and Prof. Price relied on the data contained in the Peer and the Tilanus-Linthorst papers. Subsequently, not only did Prof. Bundred revise his central opinion based on his assessment of the grading of the plaintiff's tumour and its mitotic score, but he also revised his opinion in relation to the relevance of these papers.

382. He discounted the conclusions in the Peer paper primarily on two grounds; that it was an old paper, having been written in 1993, and that it had only looked at a small number of patients who were less than 50 years of age. He discounted the Tilanus-Linthorst paper on the basis that while it had examined screening on a number of young women in Scandinavia, these were women in the high risk categories, having either BRCA1 or BRCA2 genes and/or had a high family history of breast cancer. For these reasons, he did not think that they were representative of the growth of tumours in the younger population generally.

383. Prof. Price did not agree that these papers should be discounted, or ignored. She pointed out that both papers had come to the same broad conclusion, that in general tumours grow at a faster rate in younger women. Her evidence was that no subsequent literature, or data, had emerged since the Peer *et al* paper in 1993, or the Tilanus-Linthorst paper in 2005, to cast doubt on these findings. That assertion was correct, insofar as no papers were produced by Prof. Bundred which had looked at young women and had come to a different conclusion in relation to the growth rate of tumours in young women and the appropriate tumour doubling time to take in such cases. In short, he had not produced any paper which cast doubt on the conclusions in the earlier papers.

384. Prof. Price's opinion of the continuing validity of the conclusions reached in the Peer and Tilanus-Linthorst papers, was supported by the screening programs which had been put in place in the United Kingdom, and internationally. Having regard to her role at a senior level in the management of breast screening programs at a national level, she was ideally placed to give evidence on this aspect. I accept her evidence that based on the findings in the Peer and Tilanus-Linthorst papers, while health authorities do not screen young women routinely due to the very low risk of them getting cancer, for those young women who are in the high risk categories, they are screened on a frequent basis, perhaps every year, or in some cases every six months. These shorter screening intervals are chosen because it is accepted that tumours grow faster in younger women, hence the need for more frequent screening.

385. In contrast, when one moves to the population that is over 50 years, although the risk of contracting breast cancer increases dramatically, such tumours are likely to grow more slowly, therefore, it is only necessary to perform the screening every three years, which is the standard screening interval with women in the 50 – 70 years age group. For people over the age of 70 years, there is no routine screening, because if the person does contract cancer at that age, it is likely to grow very slowly. The fact that national screening policies are done on the basis of more frequent screening at a young age, is a validation of the conclusions in the Peer and Tilanus-Linthorst papers.

386. In relation to Prof. Bundred's reasons for discounting the Tilanus-Linthorst paper, namely that these were young women who were in high risk categories and were therefore not representative of the general population, I prefer the evidence of Prof. Price, which was to the effect that while the young women were screened because they were in the high risk categories, those were merely factors which gave rise to an increased risk of them developing cancer in the first place. That was the reason why they were being screened at a young age. However, Prof. Price stated that the presence of the BRCA1 and BRCA2 genes, or the existence of a family history of breast cancer, only affected their chances of developing cancer, it did not influence the growth rate of the cancer, once it had developed. Accordingly, she stated that the conclusions in the Tilanus-Linthorst paper were relevant to the growth rates of tumours in young people generally. I find that evidence persuasive.

387. Prof. Bundred also discounted the Tilanus-Linthorst paper because he stated that it was primarily looking at interval cancers, which are cancers that emerge and develop between routine screening. Prof. Price did not agree with that assertion. What they had done, was look at serial mammography over a period of time in young women who were being routinely screened because they were in the high risk categories. When the cancer did develop, they could estimate the growth rate because there had been previous routine screening done at frequent intervals in the past. That enabled the authors to accurately estimate the growth rate of the tumour in the young women concerned. Indeed, at p. 1615 in the Tilanus-Linthorst paper, the authors specifically stated: "*Our study was performed in women with a well-defined hereditary risk, within surveillance schemes with complete follow up. The relatively low number of interval cancers (in five BRCA1 carriers only) may be due to the rather short screening intervals.*"

388. In addition, at the end of that paper, the authors were able to come to a very clear conclusion, which did not indicate that they were looking at interval cancers. Their conclusion was in the following terms: "*In conclusion, age and detection is the main indicator for growth rates of heredity and familial breast cancers. If screening may prove indicated from a certain age on, the woman's age and not the risk group should determine the screening interval. A high sensitivity biannual test may be appropriate before age 40 years.*"

389. It was also relevant that the Peer paper had looked at other studies available at that time and had concluded that their study "*has confirmed the positive correlation between age and tumour volume DT that was documented in other studies*".

390. Having regard to these matters, I am satisfied that the criticisms levelled by Prof. Bundred in his second report and in his evidence, in relation to the applicability of the data in the Peer and Tilanus-Linthorst papers, are not well founded.

391. In his second report, Prof. Bundred relied on the Michaelson paper. He maintained that because that had been a very large study of approximately 810 patients, the data contained therein was preferable to the earlier studies. In response, Prof. Price pointed out that the tumour doubling time of 130 days in Michaelson was based on a study of 111 patients, with a mean age of 61 years. That study was not based on a study of women under 50 years. As the women were older, the mean doubling time was much higher. She thought that it was inappropriate to apply that doubling time to a young woman in her early 30s.

392. I am of the view that Prof. Price's comments in relation to the Michaelson paper are apposite in this case. While it may be a very valuable study in general terms, I accept her evidence that it is not particularly relevant to younger women. In particular, the tumour doubling time of 130 days would appear to be based on a totally different cohort of patients than the plaintiff. Accordingly, I find that the data contained in the Peer and Tilanus-Linthorst papers is the more relevant in this case. While other papers were referred to in evidence, it is not necessary to go through them in detail, as they do not cause me to change that opinion of the relevance of the Peer and Tilanus-Linthorst conclusions.

393. Turning to the actual assessment of the appropriate tumour doubling time in this case, both experts were agreed that in assessing this, it was necessary to factor in a number of matters. One of these was age. Prof. Bundred felt that age ceased to be all that relevant when one knew the grade of the tumour, the mitotic score and the patient's own history post diagnosis. Prof. Price agreed that there were a number of factors which had to be taken into account, but she disagreed that age dropped out of the equation, once these other factors were known. She maintained that age always remained the dominant factor, although by no means the only one, when assessing tumour doubling time. Having regard to the literature referred to above, I prefer Prof. Price's opinion that age remains the main factor when assessing tumour doubling time.

394. Prof. Bundred primarily based his revised opinion on the grade of the tumour being Grade 2 and mitotic score of 1. He said that these were important factors, which had caused him to come to the conclusion that the plaintiff's tumour was a slow growing tumour. Prof. Price agreed that they were factors to be taken into account, but disagreed that they were highly determinative of the tumour growth rate. Insofar as Prof. Bundred had laid emphasis on the mitotic score of 1, I prefer the evidence of Prof. Price that mitotic score is but one of three factors which would be looked at by a histopathologist. It was no more important than tubule formation or pleomorphism, when assessing the overall score to determine the grade of tumour. Dr. Staunton's evidence was to the same effect. Accordingly, I do not think that Prof. Bundred's hypothesis that when one had a Grade 2 tumour with a mitotic score of 1, that that was highly suggestive of a slow growing tumour. Those factors are relevant, but are not determinative of the issue.

395. Both experts were agreed that there are a number of factors which must be taken into account when assessing the likely growth rate of a tumour. These include: grade of tumour, mitotic score, age of patient, type of tumour, and the patient's history after diagnosis. Prof. Bundred lay stress on the last of these factors, pointing out that the plaintiff had survived for longer than the usual 24 month survival period for patients who were diagnosed with metastatic breast disease. He said that this was indicative of the plaintiff having a slow growing tumour.

396. Prof. Price accepted that the usual survival time for metastatic breast disease at diagnosis, was 24 months. However, she stated that, while the plaintiff had exceeded that period by a number of months by January 2019, that was probably due to what was termed a "*treatment effect*". This patient had had very good treatment in the form of various types of chemotherapy and hormone therapy drugs, which had not been generally available at the time when the general survival time of 24 months had first been established. I find that reasoning persuasive. I find that the fact that the plaintiff has survived beyond the 24 month period initially anticipated, was probably due to the effect of modern treatment, rather than being indicative of her having a slow growing tumour. In addition on current prognosis, the plaintiff will only survive beyond the 24 month period by a number of months.

397. In support of her opinion on this aspect, Prof. Price pointed out that other measurements of the plaintiff's breast tumour carried out in the months after diagnosis, which were contained in her hospital records, indicated that the tumour was developing at a reasonably fast rate.

398. It was put to Prof. Price in cross examination that in reaching her opinion on the appropriate tumour doubling time, she had not mentioned grade of tumour in her report. She accepted that in her report she had not set out in detail all the factors which she had considered in her assessment of the appropriate doubling time. However, she stated that she had had sight of the plaintiff's records, including the histopathology report, when doing her report. She had taken account of all the relevant factors outlined earlier, including the grade of the tumour. She stated that it was specifically because of the tumour being a Grade 2 tumour, that she had arrived at her estimate of tumour doubling time at 44 – 80 days. She said that if she had discounted grade, she would have arrived at a much lower figure in terms of the tumour doubling time, possibly as low as 25 days.

399. Prof. Price stated that had she discounted grade of tumour from her assessment, she would have been at the lower end of the graph as shown in figure 3 in the Tilanus-Linthorst paper. However, she had not done that. She had factored in grade, along with the plaintiff's age, her history since diagnosis and her own clinical experience of this type of tumour and had come to the opinion that the tumour doubling time of between 44 – 80 days was the appropriate figure.

400. In reaching a determination on the issue of the correct tumour doubling time, I prefer the approach of Prof. Price. I am satisfied that in discounting age as a factor, if not completely, then substantially and by elevating grade of tumour and mitotic count to the fore, Prof. Bundred has adopted an analysis that is not supported by the literature, which, as I have already found, clearly establishes that age is a highly relevant factor. In arriving at a tumour doubling time of 130 days, or even the range given of between 100 – 130 days, I am satisfied that he has not adopted the appropriate methodology in the circumstances of this case. That tumour doubling time was based primarily on the data in the Michaelson paper, which appears to be based on a small cohort of patients, who had a totally different mean age to that of the plaintiff.

401. I prefer the analysis performed by Prof. Price. She looked at the plaintiff's age, her clinical experience of this type of tumour, the medical records, including the histopathology report giving the grade of tumour, and the patient specific factors, being her history post diagnosis, her negative family history of breast cancer, that she was progesterone receptor positive and HER-2 negative, and taking all of these factors into account has arrived at a tumour doubling time of 44 – 80 days. That is supported by the literature, which itself is accepted and used by health authorities internationally to determine appropriate screening intervals. As such, I am satisfied that her methodology and analysis is sound.

402. In these circumstances, I am of opinion that Prof. Price's estimate of tumour doubling time at between 44 – 80 days the correct one to use in this case. When that tumour doubling time is used to back extrapolate the size of the plaintiff's breast tumour in 2014, it results in a range of tumour size from 0.12cm to 0.66cm.

403. While there was some dispute as to whether one should back extrapolate from the mammographic size at diagnosis solely, or should one use other clinical findings at that time, I think it is better to work from the mammographic size, in the absence of a definitive pathological size after excision of the tumour. Accordingly, I hold that the tumour in the plaintiff's breast in 2014, was likely to have been approximately 0.6cm in size based on a tumour doubling time of 80 days. The significance of that is, that it was below the threshold size for it to have been discoverable on clinical examination by means of palpation by a GP at that time.

VII. Conclusions on the Main Issue

404. In order to reach a conclusion on the central liability issues in this case, it is necessary to begin by resolving the conflicts in evidence in relation to what did or did not happen at the consultation on 24th September, 2014. The first issue which arises is whether the plaintiff made an appointment to see the defendant, or was merely a "*walk-in*" patient, who turned up at the surgery on spec. In the course of cross examination of the plaintiff, it was put to her that the usual practice when somebody phoned to make an appointment to see a particular doctor, was that their name and the appointment time given to them and the identity of the doctor who they were going to see, would be entered in a handwritten diary. This would later be transferred onto the computerised diary at the surgery. It was put to the plaintiff that there was no record of her having made any appointment to see the defendant on 24th

September, 2014, in the handwritten diary kept at the surgery. However, the original of this diary, nor any copy thereof, was entered in evidence.

405. In response to that, the plaintiff was adamant that she had telephoned in advance of the appointment date and had received an appointment from the secretary to see the defendant at 16:00hrs on 24th September, 2014. The plaintiff stated that she had specially made the appointment to see the defendant, as she wished to be seen by a female GP, as she anticipated that an examination of her breasts would be necessary and for that reason she wished to be seen by a female doctor. It was further put to the plaintiff that 24th September, 2014, was a Wednesday and that the defendant did not usually work on Wednesdays, but was at the surgery on Mondays, Tuesdays and Fridays.

406. In the course of the hearing, the court was given a computer printout in relation to visits made by the plaintiff to the two clinics from 20th August, 2014, to 19th October, 2016. This printout recorded the arrival time of the patient at the relevant clinic, their wait time, the time the consultation started and the duration of the consultation. In respect of 24th September, 2014, it showed that the plaintiff arrived at the surgery at 15:58hrs. She was seen by the defendant at 16:00hrs. The consultation lasted twelve minutes.

407. In evidence, the defendant stated that she normally worked on Mondays, Tuesdays and Fridays, but on this occasion she was filling in for Dr. O'Connor. She could not recall exactly when she had been asked to cover his hours, but she conceded that it may have been some days in advance of that date.

408. On this aspect, I prefer the evidence of the plaintiff. I accept her evidence that having found a lump in her armpit, she had become concerned when it remained for an appreciable period of time. She then did an internet search and discovered that such a lump could be connected to breast cancer. I accept her evidence that for this reason, she specifically made an appointment to see the female GP at the practice. I accept her evidence that having telephoned the surgery, she was given an appointment to see the defendant at 16:00hrs on the day in question.

409. The absence of any entry in the written diary, while referred to by counsel in the course of cross examination, was not proved in evidence by the production of the original of the diary, nor any copy thereof. The computer printout of the patient visit history concerning the plaintiff, is supportive of her contention. I note from this printout that while waiting times in general seem to vary quite considerably, there were a number of visits where she only had to wait two, three and six minutes for her appointment. In respect of this particular visit, her wait time was only two minutes. If she had been a "walk-in" patient, meaning that she had turned up on spec, this would mean that when she turned up without any appointment seeking to see a doctor, and on a day when there was only one doctor in the surgery, there was a remarkable coincidence that that doctor happened to be free at that very moment. This meant that although she turned up on spec, she could arrive at 15:58 and be seen by the defendant at 16:00hrs. I do not think that that is likely to have happened.

410. Having regard to the evidence of the defendant, that she may have had a number of days notice that she was going to cover for Dr. O'Connor on the Wednesday, it is possible that when the plaintiff rang looking for an appointment with a female doctor, she was duly allocated an appointment time of 16:00hrs on the Wednesday. Accordingly, I find as a fact that the plaintiff did have an appointment to see the defendant on 24th September, 2014. I also find as a fact that in making that appointment, she had specifically done so in order to see a female doctor.

411. The second area of conflict in relation to the consultation is whether the plaintiff was examined while lying on the examination bed in the consultation room, with her left arm raised and her hand behind her head, as alleged by the plaintiff, or whether she was examined sitting on the bed with her left arm slightly abducted from her body and her elbow supported by the defendant, as alleged by the defendant. Both parties are agreed that the plaintiff either removed her outer top, or was able to pull it aside, as it may have been loose summer clothing, so as to reveal her axilla. Both the plaintiff and the defendant were agreed that the plaintiff did not remove her bra at any stage.

412. In relation to this conflict of evidence, I prefer the evidence of the defendant. Her evidence was that having taken the relevant history from the plaintiff, while sitting at a chair beside her desk, she asked the plaintiff to move over and sit on the examination bed. The defendant stated that it would not be appropriate to examine the axilla with the patient lying on the bed and with their arm lifted back over her head, because this would render the muscles and tissues in the underarm area taught. She stated that the method which they had been taught for examination of the axilla, was to have the patient sitting on a chair or on an examination bed with their arm slightly abducted away from the body. The doctor would support the arm at the elbow, so as to render the muscles of the axilla and upper arm lax. This was necessary to enable an adequate examination of the axilla by palpation.

413. The experts were agreed that the method as described by the defendant, was the appropriate method which would be adopted by a clinician when carrying out an examination of the axilla.

414. The defendant also stated that the examination bed was tight up against a wall. This would have meant that had the plaintiff been lying on the bed and had the defendant attempted to examine her left axilla, she would have had to approach the bed from the plaintiff's right hand side and lean over her body to carry out such examination, which would have been a more difficult way of examining the axilla. In the circumstances, I prefer the defendant's version as to how the axilla examination was carried out. Having watched and listened to the defendant carefully, it seems to me that there is no rational explanation why she would have carried out this examination by means of an inappropriate and incorrect method. Accordingly, I find that the plaintiff's axilla was examined by the defendant while she was sitting on the edge of the examination bed in the manner described by the defendant.

415. A further area of conflict between the parties was in relation to whether the plaintiff had expressed any concern at the consultation about breast cancer. Her evidence was that, having done an Internet search, she did have a concern about the lump in her armpit possibly being connected to breast cancer. She stated that she had expressed this concern to the defendant at the consultation. For her part, the defendant stated that there had been no reference to breast cancer at the consultation, except for the question which she had asked of the plaintiff, whether she had any family history of breast disease. The response to that question had been recorded in her notes. She stated that had the plaintiff expressed any concern in relation to breast cancer, she would have recorded that concern in her notes. She was satisfied that the plaintiff had not expressed any such concern to her at the consultation.

416. In resolving this conflict, I prefer the evidence of the defendant. In particular, I attach significance to the fact that there is no reference to any such concern in the defendant's contemporaneous notes. She had recorded the concern on the part of the plaintiff in relation to a possible lump in her left armpit. There was absolutely no reason why the defendant would have recorded that concern which was expressed to her by the plaintiff, but would not have recorded any other concern that was also expressed to her by the plaintiff. Accordingly, I am satisfied that the absence of any reference in her notes to the plaintiff being concerned about the

possibility of having breast cancer, or been concerned about breast cancer generally, is persuasive that no such concern was expressed by the plaintiff to the defendant on that occasion and I so find.

417. The fourth issue which arises is whether the defendant carried out an adequate examination of the plaintiff's axilla. In her evidence, the plaintiff stated that she thought that the defendant had been somewhat dismissive of her complaint that she had a lump under her arm and had carried out a somewhat cursory examination of her left axilla. She did not think that the right axilla had been examined at all. However, in cross-examination, she conceded that her views in relation to the adequacy of the defendant's examination of her axilla, had not been formed at the time of that consultation, or in the months and years thereafter. She had only come to hold that view subsequent to her diagnosis with cancer in 2016. She stated that the reason for that was that she had not really thought about the examination very much, until she thought about matters in detail some considerable time after her diagnosis with cancer.

418. The plaintiff accepted that in examining her axilla, the defendant had palpated the underarm and surrounding area extensively. When she could not find anything, she had asked the plaintiff to point out where the lump was. The defendant had used that as an indication as to where a more in depth palpation should be carried out. She had palpated the entire area again.

419. In her evidence, the defendant stated that she had palpated the left axilla on two occasions in the manner described by the plaintiff. She stated that she had also palpated the right axilla for completeness and for comparison purposes. All such clinical examinations had been negative. The defendant stated that usually consultations at the surgery were scheduled to last ten minutes. However, they often ran over, possibly up to fifteen minutes. This was possible as her list was not always full. On this occasion the visit had been recorded as having lasted twelve minutes. The defendant stated that she had examined both axillae, because she had recorded this in the plural in her notes.

420. The experts were agreed that a consultation lasting twelve minutes, would be a normal length of time in a busy GP practice and was appropriate for an axilla examination, which was estimated by Dr. Boland to take circa two minutes.

421. On this conflict, I prefer the evidence of the defendant. The plaintiff very fairly accepted in cross-examination that she did not have any complaint in relation to the way in which she had been examined in the months and years following the consultation on 24th September, 2014. It was only some considerable time later, after she had been diagnosed with cancer in 2016, that she came to the view that that consultation had been unsatisfactory. In view of the fact that the defendant had palpated the area on two occasions during that visit, I do not think that it can reasonably be held that the examination was cursory or inadequate. Furthermore, I accept the entry in her notes that both axillae were examined. That was entirely appropriate in the circumstances. Accordingly, I find as a fact that the defendant's examination of the plaintiff's left axilla was not inadequate, or done without due care and attention.

422. That brings me to the central conflict between the parties, which is whether the defendant offered the plaintiff a breast examination and whether the plaintiff refused it. The plaintiff's account is straight forward. She says that she was not offered a breast examination and therefore did not refuse one.

423. The defendant's account is that having palpated the two axillae, she said to the plaintiff in a conversational tone, "*I would like to perform a breast examination*", or words to that effect. She could not recall the exact words that she had used. She said that this request had been made in a conversational tone, so as not to alarm the patient, because in light of the negative axilla examination, she did not believe that there was any indication that the plaintiff actually had breast cancer. Furthermore, the fact that the plaintiff was a young woman and had no family history of breast cancer, meant that the index of suspicion of breast cancer was low.

424. The defendant stated that when the plaintiff declined to have a breast examination, she did not feel that she could push the matter further. She was conscious that that was the first occasion on which she had actually treated the plaintiff as a patient, although she had met the plaintiff previously, when she brought in one of her children who was sick. Given that the index of suspicion for breast cancer was low, she did not push the matter any further. She stated that she did not sense any unease or disquiet on the part of the plaintiff at not having a breast examination. She stated that she had recorded the fact that the plaintiff had declined a breast examination in her notes, which had been entered onto the computer immediately after the plaintiff left the consultation room and before she called in the next patient.

425. In looking at this conflict, one has to have regard to the fact that the plaintiff's evidence was based on her recollection of a twelve-minute consultation, which had been recalled for the first time after August, 2016 in respect of a consultation in September, 2014. The plaintiff stated that at the conclusion of the consultation, she had felt slightly embarrassed, but very relieved that she had been given the all clear by the defendant in relation to her complaint of an axillary lump. Importantly, on the plaintiff's evidence, there was nothing in that consultation which would cause her to particularly recall the consultation itself. She had not been given any bad news, which she might have ruminated on or remembered in the following two years. It was only some time after her diagnosis with breast cancer in August, 2016, that she had cause to try to recall that consultation. In opening the case, the plaintiff's counsel had stated that around the end of 2016, the plaintiff had telephoned the defendant to ascertain the date that she had seen her in 2014.

426. The defendant candidly admitted that she only had a specific recollection of two aspects of the consultation; that the plaintiff said that she did not have any relevant family history of breast cancer and that she had refused a breast examination. Other than that she had to rely on her notes, which were made immediately after the plaintiff left the consultation room.

427. A number of points can be made about the defendant's notes. Firstly, I find that they are satisfactory notes, insofar as they give sufficient detail of the relevant matters discussed at the consultation. I accept the evidence of Dr. Boland that the defendant's notes would be generally regarded as being of an adequate standard. Indeed, the plaintiff's expert, Dr. Burton, did not disagree with that conclusion, save that he felt that they would not be described as being detailed notes, due to the fact that there was not more information elicited in the history section in relation to the size and shape of the lump reported by the plaintiff and whether she had had it before, or had such lumps elsewhere in her body. I accept the defendant's evidence that she had asked relevant questions in relation to the lump, but it was her practice only to record relevant positive answers to those questions. I accept the evidence of Dr. Boland that these notes are adequate in terms of the level of detail contained therein.

428. Secondly, there was no challenge made at the trial of the action that these notes were made contemporaneously by the defendant in the manner described by her. Accordingly, I find as a fact that her notes were made immediately after her consultation with the plaintiff.

429. Thirdly, it is relevant to note that the plaintiff accepted the accuracy of certain aspects of the defendant's notes. She agreed that she had attended with a concern in relation to an axillary lump, which she stated had been present for three months and that it

was non tender. She also accepted that she had stated that she had no family history of breast cancer. All of these things were recorded in the notes.

430. Both the plaintiff and the defendant were also in agreement that the defendant had examined the left axilla twice and that she was unable to find any lump on clinical examination. Accordingly, her note is accurate in relation to the findings on clinical examination of the axilla.

431. The critical part of the notes is that portion which reads "declined breast exam". While it was put to the defendant that she had not in fact offered the plaintiff a breast examination, it was not put to her that she had deliberately written a falsehood in her notes relating to that consultation. In the course of cross-examination, it was put to the defendant that she had in fact never offered the plaintiff a breast examination. It was put to her that she was tied to a misinterpretation of her own notes, to try to provide some kind of rationale on that issue. That was the only challenge that was put to her in relation to this entry in her notes.

432. If I were to find that no breast examination was offered by the defendant to the plaintiff at the consultation on 24th September, 2014, it follows that I would have to find as a fact that the defendant had, within minutes of the conclusion of that consultation, deliberately entered a falsehood in her notes, to the effect that the defendant had declined a breast examination. That would be an extremely serious finding to make against a doctor. It is only fair that if such a finding was to be made against a practising medical practitioner, at the very least, the allegation should have been put to them in clear terms and they should be given an opportunity to deny or explain that allegation, prior to any adverse finding being made against them.

433. The law in relation to the duty to put matters to witnesses in cross-examination has been long established at common law. In *Browne v. Dunn* [1894] 6R. 67, Herschell L.C. set out the rationale for this rule of evidence in the following terms at pp. 70-71:

"Now, my Lords, I cannot help saying that it seems to me to be absolutely essential to the proper conduct of a cause, where it is intended to suggest that a witness is not speaking the truth on a particular point, to direct his attention to the fact by some questions put in cross-examination showing that that imputation is intended to be made, and not to take his evidence and pass it by as a matter altogether unchallenged, and then, when it is impossible for him to explain, as perhaps he might have been able to do if such questions had been put to him, the circumstances which it is suggested indicate that the story he tells ought not to be believed, to argue that he was a witness unworthy of credit. My Lords, I have always understood that if you intend to impeach a witness you are bound, whilst he is in the box, to give him an opportunity of making any explanation which is open to him; and as it seems to me, that is not a rule of professional practice in the conduct of a case, but is essential to fair play and fair dealing with witnesses."

434. Halsbury L.J. explained the principle in similar terms at pp 76-77:

"To my mind nothing would be more absolutely unjust than not to cross-examine witnesses upon evidence which may have been given, so as to give notice and to give them an opportunity of explanation, and an opportunity very often to defend their own character, and, not having given them such an opportunity, to ask the jury afterwards to disbelieve what they had said, although not one question has been directed either to their credit or to the accuracy of the facts they have disposed to."

435. The principles set out in the *Browne* case were accepted as being a correct statement of the law by Laffoy J. in *McNamee v. Revenue Commissioners* [2016] IESC 33. Those principles were also accepted by Charleton J. in *McDonagh v. Sunday Newspapers Limited* [2017] IESC 46, where, having cited the cases referred to above, he stated at para. 41:

"The extent to which fairness requires cross-examination is essentially dependant on how a trial runs. Fairness, however, is what the law requires both in relation to procedures that are dedicated towards achieving a correct conclusion in a trial and in relation to the right of a witness to be given a real opportunity to comment on a verdict the implication of which may only be interpreted as adverse."

436. Those statements of the law were also accepted by this Court in *Browne v. Van Geene* [2017] IEHC 612 and in *Jedrusch v. Tesco Ireland Limited* [2018] IEHC 205. Having regard to the state of the law, I am of opinion that two consequences flow from the failure to put the allegation to the defendant that she had deliberately written an untruth in her notes. Firstly, objection could have been taken by counsel on behalf of the defendant, that had the plaintiff sought to put such an allegation to any witnesses called after the defendant had given her evidence. Secondly, the specific allegation could not have been put before a jury, or before the trier of fact, if such allegation had not been put to the witness. Accordingly I am of the opinion that I would not be entitled to make any finding that the defendant had deliberately written a falsehood in her notes in relation to the plaintiff declining a breast examination, as that specific allegation was not put to her.

437. However I do not rest my judgment solely on this somewhat technical ground. Even if it had been put to the witness and denied by her, having watched the defendant carefully giving her evidence, I am satisfied that she would not deliberately write in her notes that the plaintiff had declined a breast examination, if that was not the case. I simply do not accept that she falsified her records.

438. I am fortified in that conclusion by the fact that there was no reason for her to enter such a falsehood in her notes. If she had for some reason omitted to offer the plaintiff a breast examination and had realised that in writing up her notes immediately on the departure of the plaintiff, there was no need for her to falsify her records; all she had to do was ask her secretary to contact the plaintiff and ask her to come in for a breast examination on the following Friday, or in the following week. There was absolutely no need for her to falsify her records, which would be a very serious thing for a doctor to do.

439. In relation to the defendant's testimony generally, she gave her evidence in a clear and straight forward manner. She did not try to dodge any difficult questions, nor did she try to obfuscate in her answers. I am satisfied that she is essentially an honest witness.

440. On this conflict of evidence, I prefer the evidence of the defendant that the plaintiff declined a breast examination after the negative axillary examination. That evidence is supported by her notes, which were made contemporaneously. There is no evidence that would enable me to hold that the notes are not truthful or accurate. On this aspect, I prefer the evidence of the defendant which is supported by her contemporaneous notes. Accordingly, I find that a breast examination was offered and was declined by the plaintiff at the consultation on 24th September, 2014.

441. In saying that, I am not casting doubt on the plaintiff's honesty, the doubt is solely in relation to the accuracy of her recollection. I am satisfied that her recollection of the consultation in this regard is mistaken. That may have been due to the fact that it was over two years later, when she had been sucked into a vortex of terrible diagnoses, with a devastating prognosis, that

she first recalled certain aspects of the encounter, namely that she had attended the defendant with a concern about a lump in her axilla and that her breasts had not been examined on that occasion; both of which were true, but she wrongly came to the conclusion that that meant that no breast examination had been offered. Accordingly, I am satisfied that the plaintiff was merely mistaken in her recollection of what occurred at the consultation, rather than there being any deliberate attempt on her part to give false evidence.

442. In the course of cross-examination, it was put to the defendant and to other witnesses, that if a young woman had found a lump in her axilla, had done an internet search and discovered the possible link between such a lump and breast cancer and had specifically made an appointment to be seen by a female GP, with a view to having a breast examination, there was no rational reason why she would have refused one when offered it. Broadly speaking, the witnesses, including the defendant, agreed with that proposition. At first glance, there is certainly considerable strength in it. However, for reasons that will become clear presently, I am of the opinion that a refusal of a breast examination by the plaintiff on this occasion, may not have been such an irrational or unlikely outcome.

443. The next conflict between the parties, was whether there was consensus between the plaintiff and the defendant that there was no lump present in her axilla on 24th September, 2014. There was a fairly stark conflict between the evidence of the plaintiff and the evidence of the defendant on this aspect. The plaintiff maintained that she was able to feel the lump in her axilla at all times, including during the consultation and indeed during the two years thereafter.

444. The defendant's evidence was to the effect that, having thoroughly palpated the axilla on two occasions during the consultation, there was a consensus between them that there was no lump present. The defendant stated that at no time did the plaintiff verbally communicate to her that she thought that the lump was still present. Nor did she get any sense from the plaintiff's body language, or otherwise, that she thought that the lump was still present, despite the negative clinical examination of the axilla by the defendant.

445. Having considered the evidence of the plaintiff and the defendant on this issue, I prefer the evidence of the defendant for the following reasons: firstly, I accept the defendant's evidence that the plaintiff did not verbally communicate any concern that she could still feel the lump. The plaintiff did not state in evidence that she had specifically told the defendant that the lump was still there. I also accept the defendant's evidence that had she done so, it would have been recorded in her notes and the consultation would have taken a different direction. I also accept the defendant's evidence that she did not pick up any sense of disquiet or disagreement on the part of the plaintiff with her conclusion following clinical examination, that there was no lump present.

446. The absence of any entry in the notes of any disagreement or concern on the part of the plaintiff that the lump was still present, is supportive of the defendant's evidence in this regard. One must also take into account that the presence of a disagreement between a doctor and their patient in relation to the presence of a certain condition, such as a lump, is not something that reflects badly on the doctor. If there had been any disagreement between the plaintiff and the defendant, there was no reason why the defendant would not have recorded such lack of consensus in her notes. Accordingly, I regard the absence of any such entry in the notes as being significant.

447. There was also a positive entry in the notes which supports the defendant's account. According to the notes, at the end of the consultation, the plaintiff was told to return if the lump should recur. This was recorded as "TCI if recurs". The use of the word "recurs" in its ordinary meaning suggests that there was no lump on that examination, but if it should come back, the patient should return to the surgery. While the plaintiff stated in evidence that she had no recollection of any such advice being given to her towards the conclusion of the consultation, I prefer the accuracy of the written notes made contemporaneously and accordingly I find that such advice was given. The giving of such advice is supportive of the fact that there was consensus between them that there was no lump present at that time.

448. There are two further elements in the conduct of the plaintiff which are supportive of this conclusion. Firstly, the plaintiff was seen on approximately ten occasions between 24th September, 2014 and 16th August, 2016, when she went to Dr. Redahan about the lump in her breast. On three of these occasions she was reviewed by the defendant in relation to other complaints. On other occasions she was seen by different female doctors in a different clinic. On no occasion did she mention the lump to any doctor.

449. At the trial an attempt was made to explain this state of affairs by the assertion that, while the lump had persisted throughout the entirety of the intervening two years, the plaintiff had not worried about it, or mentioned it to any doctor, because the defendant had reassured her that it was nothing to worry about. I find that somewhat difficult to believe. If the lump had persisted for the entire two years after September, 2014, and during that time the plaintiff had been seen by different doctors in different clinics, I feel that on the balance of probabilities, even if only for reassurance, the plaintiff would have mentioned it to one of these doctors.

450. Of more significance, is the fact that when the plaintiff went to see Dr. Redahan in relation to the lump in her breast and knowing from her internet search that there was a possible connection between breast cancer and axillary lumps, it is significant that she did not mention to Dr. Redahan that she had had a lump in her axilla for over two years. I find it improbable that if she had had a lump in the axilla for that period prior to August, 2016, she would not have mentioned that to Dr. Redahan.

451. I have also had regard to the fact that no lump was found on clinical examination of the axilla by either Dr. Redahan, or Mr. Allen in August, 2016. If they could not find any lump in the axilla, which they were specifically looking for in the context of a positive finding of a lump in the breast, I do not think that the plaintiff could have felt it either.

452. Lastly, I accept the evidence of Prof. Price, that having regard to the various findings on clinical examination in August and September, 2016 and on the scanning undertaken in 2016, and having regard to the finding on ultrasound of mild cortical thickening in the axilla, and having regard to the amount of malignant disease in the node at that time, it was unlikely that the plaintiff had had an enlarged node in 2014.

453. For all these reasons, I prefer the evidence of the defendant that there was in fact a consensus between her and the plaintiff at the consultation on 24th September, 2014, that no lump was present in her axilla on that occasion.

454. In light of that finding, the declining by the plaintiff of the offer of a breast examination becomes more credible. It is certainly possible that, having gone to the doctor about a lump in her axilla, which could not be found by the doctor on careful examination and when the plaintiff was in at least tacit agreement that there was no lump present, when the offer of a breast examination was put to her in conversational tones, it is understandable that she may have declined such offer, as she did not have any concern about any lump in her breast at that time. This would also fit with her description of her feelings at the end of that consultation, that she was a little embarrassed to have troubled the doctor, but was relieved that nothing of concern had been found.

455. In light of these findings, one has to consider whether the defendant was negligent in either not insisting more strongly at the consultation on 24th September, 2014, that the plaintiff should have a breast examination, or whether she should have scheduled a review appointment some weeks later.

456. In relation to the first question, I accept the evidence of Dr. Boland, that having regard to the fact that there had been a negative axilla examination, a consensus between the doctor and the patient that there was no lump present on that occasion and in light of a plausible explanation for that state of affairs, being that there may have been a transitory inflamed or enlarged node due to her longstanding eczema, and in light of the plaintiff's age and negative family history, it was reasonable for the defendant not to push the issue of a breast examination once it had been declined by the plaintiff.

457. Accordingly, I find that the defendant was not negligent in failing to make a second or more vigorous request to examine the plaintiff's breasts at the consultation on 24th September, 2014.

458. In relation to the question of whether the defendant should have told the plaintiff to return for review in a few weeks, Dr. Burton's opinion that that should have been done, was predicated on an assumption that notwithstanding the negative axilla examination, the plaintiff had still maintained that a lump was palpable and that if the defendant was not specifically made aware of that, she was, at least, aware of a lack of consensus between her and the plaintiff on that issue. Essentially, Dr. Burton and Dr. Boland were in agreement that if there was no consensus between the plaintiff and the defendant in relation to the presence of a lump, then a review was mandated.

459. However, where there was consensus, as I have found to have existed on this occasion, the evidence of Dr. Boland was that it was not necessary to schedule a review appointment; it was sufficient to give advice to the patient to return if the lump should recur. I accept that evidence and as I have found that that advice was, in fact, given, I find that the defendant was not negligent in failing to arrange a review appointment for the plaintiff some weeks later.

460. Nor do I accept that the defendant's actions were in breach of the National Breast Cancer GP Referral Guidelines, issued by the HSE in April 2009. The advice given on p. 2 clearly states what should be done if a patient attends with a GP complaining of a breast lump. It stipulates that a full history should be taken, followed by an examination of the breasts. If no lump was found, the guidelines state "*Reassure ?Reassess*". At the trial, it was maintained on behalf of the plaintiff, that the phrase "breast lumps" at the top of column 2, where that advice was given, included circumstances where a patient attended complaining of an axilla lump. This proposition was based on the fact that on p. 1 which refers to the different types of referrals that may be made, under the heading "*Urgent Referrals*", it provided that where a discreet breast or axillary lump was found, there should be an urgent referral.

461. I am satisfied that the reference to axillary lumps on p. 1, is in fact against the proposition put forward on behalf of the plaintiff. I am of opinion that if axillary lumps were to be included in the algorithm provided on p. 2 of the guidelines, axillary lumps would have been specifically stated, as had been done on page 1. There is no reason why such lumps would not be mentioned, if it had been intended to include them on page 2.

462. I prefer the evidence of Dr. Boland to the evidence of Dr. Burton that these guidelines, when referring to "*breast lumps*" on p. 2, do not include situations where patients complain of an axillary lump, but none is found. Dr. Boland's evidence that the understanding of Irish GP's of these guidelines is to the effect that the advice given on p. 2 does not include circumstances in relation to a complaint of an axillary lump, is persuasive.

463. I also accept the evidence given by Dr. Boland that if a patient was concerned about an axillary lump, but none was found on clinical examination and the plaintiff was happy with that conclusion, it was only necessary to reassure the patient and advise her to return if the lump should recur. That was what was done in this case. Accordingly, even if the guidelines on p. 2 did apply to this case, the defendant had complied with them. Dr. Burton stated that if the Court accepted that the defendant's notes were accurate, then he agreed with the opinion of Dr. Boland that there was no breach of the guidelines by the defendant.

464. Having regard to my findings in relation to what transpired at the consultation on 24th September, 2014, I am satisfied that the defendant was not negligent in failing to raise the issue of the axillary lump when she saw the plaintiff on subsequent occasions.

465. Finally, even if I am wrong in relation to my conclusions that there was no negligence on the part of the defendant and if the defendant had been negligent in failing to carry out a breast examination on 24th September, 2014, that did not lead to any loss or injury, because having regard to my findings on the technical issue, I am satisfied that having regard to the probable size of the breast tumour in 2014, it would not have been palpable on clinical examination at that time. In other words, had the defendant examined the plaintiff's breasts on 24th September, 2014, I am satisfied that on the balance of probabilities she would not have found any lump in the breast. In such circumstances, where there would have been negative breast and axillary examinations, then the defendant would, without any negligence on her part, simply have reassured the plaintiff that all was well. No further investigation would have been carried out at that time. However, in view of my primary findings in this case, this aspect does not require further elaboration.

466. For the reasons set out herein, and having regard to the principles laid down in *Dunne (An Infant) v The National Maternity Hospital* [1989] IR 91 and *Collins v Mid-Western Health Board* [2000] IR 154, I find that the defendant did not act negligently in her care of the plaintiff. Accordingly, I dismiss the plaintiff's case against the defendant.