

THE HIGH COURT

[2023] IEHC 194

Record No. 2020/5533P

BETWEEN

CATRIONA CRUMLISH

Plaintiff

-AND-

HEALTH SERVICE EXECUTIVE

Defendant

Judgment of Ms. Justice Mary Rose Gearty delivered on the 14th of March, 2023

1. Introduction and outline facts

1.1 This is a medical negligence case which turns on a causation issue: whether the size of the Plaintiff's tumour at a point in time can be estimated reliably by using statistical data and a mathematical formula. She seeks damages for injuries caused when her doctors failed to diagnose breast cancer in May of 2017. It is not in issue that the Plaintiff had cancer in May, but it was not diagnosed until the following October. The Plaintiff's argument is based, in large part, on an academic paper which analysed the growth rate of breast tumours. The use of the data presented in that paper, and the application of its authors' conclusions to this case, have been strongly contested.

1.2 The Plaintiff also argues that the clinician and radiologist employed by the Defendant failed to adhere to all the required steps of triple assessment in a breast cancer clinic, which is why her cancer went undetected. In an argument closely related to that issue, it is submitted that there was no concordance between the results of clinical and radiological examinations in her case. This, she submits, should have

led to further investigation, whether by further clinical examination or by histopathological investigation. Either of these responses would have achieved concordance in respect of identifying the entity in her breast in May 2017.

1.3 The Plaintiff submits that, in the absence of these failures, her cancer would have been diagnosed earlier, she would not have had nodal removal surgery and would not have suffered related adverse effects. The Plaintiff seeks damages in respect of pain, loss of earnings, the cost of childcare, and loss of pension entitlements occasioned by a consequent reduction in her life expectancy.

2. Legal principles: medical negligence and the role of the expert

2.1 The leading authority on the standard of care required of medical practitioners in Ireland is *Dunne v. National Maternity Hospital* [1989] I.R. 91, applied recently by the Supreme Court in the case of *Morrissey v. Health Service Executive* [2020] IESC 6.

2.2 The right to damages is established by a Plaintiff when she proves not only that she was treated negligently in that the care afforded to her fell below the standard expected of a professional of like skill, but that this negligence caused her to suffer loss and damage. If the entity which was detectable in May of 2017 was not cancer, then even if negligence is established, whether by failure to carry out all stages of triple assessment of the lump or by failure to achieve concordance as to what it was, no damage was caused as taking these steps would not have revealed the tumour which was found in October.

2.3 Expert evidence was considered in the recent case of *Duffy v. Brendan McGee & Anor* [2022] IECA 254, where Noonan J. and Collins J. delivered judgments in respect of the role of the expert. The *Duffy* case confirms that the decision as to which opinion carries most weight remains with the Court. The premises on which the opinion is based, the opinion itself, and the expert's evidence when questioned about that

opinion should be considered in deciding what weight to attach to the views of any expert. The role of the expert is to give independent advice to the Court and, if her evidence appears to lose that character, this will usually affect the weight of the evidence. The dramatic circumstances in which the expert's evidence was given in *Duffy* are rare but it is a common, and very human, feature of expert evidence that a witness who should be independent may espouse the views of the instructing team more closely than is ideal.

3. The Modular Trial Issue

3.1 The Defendant sought an Order separating this trial into two modules, the first dealing with liability and causation, and the second, if it arose, dealing with quantum of damages. The Defendant, arguing that the issue of quantum would take twice the time of a liability hearing, relied on *Cork Plastics v. Ineos Compound* [2008] IEHC 93, Clarke J. and *McCann v. Desmond* [2010] 4 I.R. 554.

3.2 In *Cork Plastics*, Clarke J. held that the default position “*is that there should be a single trial of all issues at the same time*”. In such applications, the first factor to consider is the complexity and length of the likely trial. Other factors to be taken into account include effects on an appeal, overlaps in evidence, witnesses who are not relevant to all issues, the effect of liability findings on damages and the issue of prejudice.

3.3 This Plaintiff argued that the principles emerging from *Cork Plastics* and *McCann v. Desmond* suggested that there should be an issue which can be separated cleanly from others arising in the case.

3.4 In a similar application for a modular trial in *Freeney v. Health Service Executive* [2020] IEHC 719, Hyland J. held that although there were two witnesses identified by the Plaintiff relating both to liability and quantum, there were very significant numbers of witnesses on both sides who were going to give evidence in respect of

quantum only. While conscious of the position of a Plaintiff who might have to give evidence twice, she allowed the application.

3.5 Adopting the same rationale, this Court ruled at the outset of the hearing that while the default position was to prefer a unitary trial and it would be unpleasant for this Plaintiff to give evidence on multiple occasions, as it would be for any plaintiff, there was a clear saving of time and costs in treating the two aspects of this case as being different modules of the same hearing. Furthermore, while it was clear that at least two witnesses would give evidence that may be relevant to all issues, the majority of witnesses could be categorised as offering evidence relevant to questions of liability or questions of quantum, but not both.

4. The Plaintiff's relevant medical history

4.1 At the end of March 2017, the Plaintiff felt two hard lumps in her right breast, one comparable in size to a pea, the other to a peppercorn. Her husband and her General Practitioner could also feel these two lumps. On the 31st of March 2017, the Plaintiff's G.P. referred her to Letterkenny University Hospital [LUH], where she attended on the 4th of May. The Plaintiff was examined by Mr. Sugrue, the clinician in charge of the LUH triple assessment breast clinic. She was 35 years old at this time.

4.2 Triple assessment refers to the internationally accepted practice of assessment in order to ensure the most effective results in treating symptomatic breast cancer: clinical, radiological and histopathological assessment of the breast. At each stage, the patient is assessed and a letter and number assigned to the result. The first assessment is clinical, then radiological and then, if the clinician and radiologist do not agree that there is no cause for concern, a biopsy may be taken for histopathological tests.

4.3 The letter used as shorthand for these assessments identifies the relevant specialist: S denotes the clinician or surgeon, R the radiologist and P the pathologist.

The lowest number, 1, is assigned where nothing is found. The highest, 5, is reserved for situations where malignant growths are identified. So, for example, S1 is a normal finding, S2 is benign, S3 indicates entities found, probably benign but cancer is not ruled out and S4 is suspicious for cancer with S5 indicating malignancy. The same scale applies to numbers R1 to R5 and P1 to P5. If the numbers are not concordant, this suggests that the specialists disagree as to what the entity is or what risk it presents. The lump examined in this case was assessed as S3 by Mr. Sugrue. It was designated R2 by the radiologist, Dr. Mac A'Bhaird.

4.4 Mr. Sugrue noted what he described in the records as a 15mm lump, the pea-sized lump, in in the lower outer quadrant of the Plaintiff's right breast. He could not palpate the smaller, peppercorn lump. He measured the position of the pea-sized lump with a ruler, noting that it was 10cm from the nipple in the 8 o'clock position, looking at the breast as a clock face. The medical notes include a template diagram with a simple line drawing of a female torso allowing the clinician to draw a circle, as Mr. Sugrue did, showing exactly where on the right breast this lump could be found.

4.5 The lump was also marked on the Plaintiff's breast by Mr. Sugrue. He then referred the Plaintiff to the next phase of triple assessment: radiology. Here, images are taken by mammogram and by ultrasound. The ultrasound examination was performed by Dr. Mac A'Bhaird. The result of the patient's mammogram had already been provided to him and there was no sign of any suspicious entity but, as all witnesses agreed, it was unlikely that anything significant could be viewed on mammography which does not function well as a diagnostic tool where the relevant tissue is dense, as it was in this case and as is normally the case in younger women.

4.6 An ultrasound is undertaken by moving a probe around the skin on the relevant area whereby the tissue below is shown on a screen beside the operator. This radiological tool is much more effective than mammography at identifying cancerous growths and distinguishing them from simple cysts which are often found in the

breast and which pose no risk. Here, the relevant area was the lower right quadrant of the right breast, as marked on the pea-sized lump by Mr. Sugrue. The operator, Dr. Mac A' Bhaird, sees the ultrasound results on a screen and in real time and can move and pause the picture on screen. He can also take photographs, effectively, and several such screen shots were exhibited. Any measurement that is taken is accurate as the software allows callipers to be placed on each side of any entity which is detected and automatically reads the diameter allowing a record of millimetres to be taken. One can see the muscle of the chest wall and the skin surface, thus the location of the entity in the breast is clear to the operator, and often these landmarks appear on the screenshots also.

4.7 The live picture of the moving tissue on the screen is clearer than the images retained and the entities appear in higher definition. Dr. Mac a Bhaird's report on what he saw in the Plaintiff's breast was: "*[r]ight breast, multiple small cysts up to 12mm in LOQR [lower outer quadrant right]*". As noted, this result was designated 'R2' or benign, according to the relevant guidelines.

4.8 Immediately after the ultrasound, and while she was still in the room with gel on her breast to facilitate the operation of the probe, the Plaintiff recalls Mr. Sugrue coming in to talk to Dr. Mac a Bhaird. She heard one of them use the phrase "*unusual cluster in the lower quadrant*". The Plaintiff was then reassured by Mr. Sugrue that she had cysts, and that while they may grow larger or smaller, she should not worry.

4.9 In the following months, the Plaintiff's impression was that the lumps got bigger and joined together in an 'oblong' shape. In August of 2017, she found a lump in her armpit, and on August 15th she attended her G.P., who referred her to LUH again. On the 29th of September, she found a second lump somewhat lower down from the armpit on her right side, and her appointment was expedited.

4.10 The Plaintiff returned to LUH on 9th October 2017. As part of the clinical examination, Mr. Sugrue found a lump, which he noted as being in the 6 o'clock

position in the same quadrant of the same breast. The lump measured 4cm from the nipple on this occasion and was deeper in the breast, according to Mr. Sugrue's evidence in which he relied on his notes. Again, these notes are accompanied by the diagram which illustrates the position of the lump on the patient's breast. Following radiological assessment, the radiologist, Dr. McGowan, sent the Plaintiff for a biopsy.

4.11 While Mr. Sugrue and a breast care nurse advised the Plaintiff on the 9th of October that what was there was growing fast, the word cancer was not used on that date. She was shown images from May and October and she understood that this was to see its progression. Mr. Sugrue told her that he would fast-track the biopsy results.

4.12 On Thursday 12th October 2017, Mr. Sugrue confirmed that the Plaintiff had HER2-positive breast cancer. HER2 is a protein promoting the growth of cancer cells. HER2-positive cancer was often fatal until recent decades when cancer research and trials led to better treatment options. The tumour was bi-lobed, with two apparent foci, the larger part of the mass measured 34mm, the other part was 11mm at its widest point. Mr. Sugrue advised neoadjuvant chemotherapy, which term means that treatment takes place in advance of surgery to remove the tumour.

4.13 On 9th November, chemotherapy commenced. The Plaintiff had a double mastectomy on the 12th of April 2018. Pathology on the tissue removed during surgery showed that the chemotherapy treatment had worked well. There was significant lymph node removal as part of the surgery. This was from an area reaching from the Plaintiff's elbow to her armpit. Adjuvant radiotherapy, in other words radiotherapy treatment supplemental to her surgery, then commenced. The Plaintiff attended radiotherapy weekly for 5 weeks. Happily, the Plaintiff is now cancer free.

4.14 During 2018, the Plaintiff did not have any particular concerns about the manner of her diagnosis. She did wonder if the cancer had been there in May, but treatment was her focus rather than analysing the history of her illness. She had counselling at the end of 2018 with Cancer Care West. In a letter written a year after

the first diagnosis, dated 9th October 2018, Mr. Sugrue was asked by the Plaintiff's G.P. to meet with the Plaintiff or to arrange for her to meet the breast care nurse. While the Plaintiff did not recall a specific response to that letter, Mr Sugrue appears to have written back in December 2018 saying that he had met her for assessment at the North West triple assessment clinic in October.

4.15 The Plaintiff was seen that October and was examined physically. She was told (apparently on the phone) that she would be seen in a year's time. The Plaintiff does remember the advice to return in a year, as she was surprised. She phoned the breast care nurse (the Plaintiff recalls being in the car park of a toy shop at the time) to discuss this response and said she was panicking slightly at that stage. She had attended regular appointments for treatment until then and felt she had, in her words, been released but without a parachute. Her nurse encouraged her to move on, but she felt nobody understood. There was no reference to her G.P.'s letter requesting a meeting, there was no "debrief" and the review in October 2018 was a standard one.

4.16 The Plaintiff's witnesses insisted that the lump palpated in May should have been aspirated with a fine needle so that it could be identified with greater certainty. Had this been done, it is said, her cancer would have been detected in May. There was a second, related argument that concordance between the designated numbers must be recorded and, if a number is changing, a reason must be given. If not, investigations should continue. For example, if an entity is found on clinical examination and, as here, is assessed as S3, under the relevant guidelines, this means that it is "indeterminate – probably benign". In that case, according to the Plaintiff, recording a radiological score of R2 is insufficient without further investigation. The numbers do not match and one of them is S3 which does not rule out cancer. If the clinician is changing his view and moving from S3 to S2, it is argued, this should be recorded along with the reason for the change.

4.17 Before any alleged negligence can be considered, however, the Plaintiff must establish that the larger lump she palpated in her breast in May was a tumour. If that cannot be established, or if it is likely to have been a cyst, then the failures described, whether or not they constitute negligence, probably did not cause the alleged injuries.

5. Agreed facts in respect of the Tumour in October

5.1 In October of 2017, three biopsies were taken from the Plaintiff's right breast. The Plaintiff had poorly differentiated invasive ductal carcinoma. This tends to grow and spread faster than a lobular cancer. The lobule produces milk in the breast, which then travels down in a duct to the nipple. If the tumour originates in the duct, it is a ductal cancer, if it forms in the lobule, it is a lobular cancer. Ductal cancers tend to form a solid lump and are more common. A poorly differentiated cancer is more diffuse than a well differentiated cancer. If a cancer is growing slowly, it tends to be well defined in terms of its visible shape. If it is growing rapidly, it is poorly differentiated and is unable to maintain its original anatomical structures. This cancer appeared as a bi-lobed, or two-part, mass, measuring 34mm and 11mm.

5.2 As noted, the cancer was HER2-positive, which refers to a protein that promotes growth. This cancer was ER and PR negative, referring to two hormones, estrogen (or oestrogen) and progesterone, and the receptor cells associated with them. There are hormone receptors found in cells in the breast. When a cancer cell is replicating, if it is replicating slowly, it will reproduce all the features of the host cell, including the hormone receptor on the surface of the cell. If there is no such receptor in the cancerous cell, this suggests that it is replicating too fast to reproduce it.

5.3 The mitotic frequency of the cells refers to the frequency of cell division. The mitotic frequency score was high: 3, out of a possible range from 1 to 3. The grade assigned to this cancer was Grade 3, the worst grade in terms of the aggressive nature of its growth. The proliferation marker is referred to as the Ki 67, which was 75%.

Usually, this figure is 20%. Finally, the Plaintiff was only 35 years old and breast cancer tends to grow faster in younger women. These features all suggest that the cancer detected in October was very aggressive and growing at a very fast rate.

6. Memory, Records and Routine

6.1 Neither Mr. Sugrue nor Dr. Mac a Bhaird recalled the patient's visit in May of 2017. This Court takes the view that this is quite normal, given the number of patients seen at the clinic and the decision to discharge the Plaintiff back to her G.P. In other words, this should not have been a memorable meeting for any reason so there is nothing sinister in the fact that neither man can recall it. The two medical witnesses as to fact are therefore dependent on their records of these events and, to a lesser extent, on their general practice. By this I mean that while they can of course recount what they usually do, they cannot confirm what was actually done in this case unless it is supported by the medical records.

6.2 Where the Plaintiff's recollection differs from what they say is their usual practice, the Plaintiff probably has the better recollection of certain events of that day on the basis that this was an unusual and memorable event for her but not for them. As the Plaintiff made no note or record of her attendance or of subsequent events, however, surrounding evidence, including the medical records, must also be considered in resolving any dispute which may arise in this regard. Medical notes, written at the time of the events they record, carry significant weight unless there is a reason to doubt their accuracy. There is little dispute between the parties in respect of most of the facts, however. In answer to cross-examination, the Plaintiff agreed with many of the matters put to her which were subsequently confirmed by the two doctors when they gave evidence. Likewise, their evidence was broadly in line with hers as to fact.

6.3 Many of the systems used by Mr. Sugrue are exemplary. The emphatic points at the outset of each of his letters to highlight any issue arising to the G.P., are useful and ensure the key points are made clearly. He takes meticulous measurements; so much so that he uses a ruler as well as marking the breast itself and drawing an accompanying diagram. He tends to dictate his letter to each G.P. in the presence of the patient so that she knows its contents.

6.4 It is not in dispute that there was a lump in the Plaintiff's breast in May of 2017. Nor is it disputed that G.P. and the Plaintiff herself could feel two lumps. Whether there were one or two lumps is of minimal relevance in the overall context of this case and it was not contested that there were probably two lumps. The single lump that Mr. Sugrue could feel was assessed as S3 or "indeterminate". In other words, it was not clear if this lump was, or was not, malignant.

6.5 When the Plaintiff was sent to the radiologist, Dr, Mac A'Bhaird, for imaging in May, it is agreed that he had the benefit of the mark made by Mr. Sugrue at the point on the breast where the largest lump had been felt and that this mark was at the correct location, so there is no issue about where the ultrasound examination focus was: on the right lower quadrant of the breast specifically at the site of the palpable lump positioned at 8 o'clock, 10 cm from the nipple. The evidence also reveals no issue about the length of time that the examination took or the accuracy of the ultrasound as a mechanism for identifying certain types of cancer above a certain size: it is excellent and is particularly accurate in the hands of an experienced operator. As noted, the pictures produced by his screenshots are not as clear as the picture on the screen in real time while the probe is being used to examine the breast.

6.6 While the Plaintiff was still in the room after the ultrasound, she recalls that Mr. Sugrue came in and had a discussion which appeared to be about the imaging in her case. The records suggest that Mr. Sugrue confirmed that the radiographer had examined the marked area. This can be deduced from a handwritten note on the

report to that effect. The typed note, prepared first, referred only to cysts but a handwritten addition added the words “in the marked area”. I am satisfied that this was probably the subject of the conversation, although neither man can remember the events of that day.

6.7 During the conversation, the Plaintiff recalled hearing the words “an unusual cluster”. Neither man could explain that phrase. There was a number of cysts (at least 5) but that in itself is not unusual, as cysts are a normal feature in a woman’s breast. It may be that the Plaintiff, not having taken any notes at the time, has mistaken what was said or has not recalled exactly the words that were used. It may also be that the phrase was used but, if it was, it is difficult to link this to any misdiagnosis.

6.8 If the words “an unusual cluster” were used, this Court cannot interpret this as meaning anything significant in terms of the diagnosis or presence of a tumour at that time, which is the basis of the Plaintiff’s case. There was no expert evidence which suggested that this phrase was, or could be, relevant to the issues in the case. The Plaintiff’s case is not that the two men noticed something unusual and tried to cover it up and, plainly, such a theory would be not just speculative but baseless. Given this context, there is no reason for the Court to decide whether the words were used at all.

6.9 The radiologist confirmed his routine practice of examining an area closely and in different planes, that is, he used the probe sweeping left to right and again up and down across the marked area in each case. Any entity seen was measured using the software callipers on the screen. His practice was to mark simple cysts as R2, as they are invariably benign. He marked complex cysts or fibroadenoma as R3 because these might conceal or disguise something more sinister. Tumours were designated R4 or R5, depending on his level of certainty as to what he was viewing. If nothing was seen, it was an R1 finding. In the case of an R3, he would biopsy the entity without further reference to Mr. Sugrue.

6.10 There was an argument that the radiologist had drawn only 4 circles on his diagram of the breast but purported to find 7 cysts. Having looked at this diagram, I am satisfied that the drawing was representative and that, particularly given the size of the pictured breast, it would be difficult and unnecessary to draw 7 circles in the small quarter of the diagram so there is no substance to this criticism of the report.

6.11 The evidence from all experts was consistent in respect of the visual appearance of simple cysts, which are very different in appearance from tumours. Fluid is black on ultrasound images, making the fluid-filled cysts easier to distinguish from tumours, which are grey, to put it very simply. A cyst also tends to be well defined, with a smooth border, unlike most cancers.

7. Summary of the Arguments: what was the pea-sized lump?

7.1 The Plaintiff confirms in submissions that her argument is confined to “the sole symptomatic and largest lump of which no image was taken”, i.e. the pea-sized lump. It is argued on her behalf that this was cancer and not a cyst. It is submitted that the theory that the tumour in October was an interval cancer is contradicted by the Defendant’s own expert’s report, which suggests that the Plaintiff not only had a tumour in May 2017 but that she was also node positive by that stage. That expert’s refusal to express a view on whether there was a delayed diagnosis is also highlighted.

7.2 The Plaintiff submits that her position is supported by an argument about location, namely, that the tumour in October is, according to the Plaintiff, in the same position in the breast as the pea-sized lump in May. The MRI in particular is relied upon in this regard, as is the evidence of the Plaintiff that the pea-sized and peppercorn lumps did not go away but merged and became bigger. The submission was made that it could not be a coincidence that the lump and the tumour appeared in the same quadrant of the breast.

7.3 The Plaintiff also urges the Court to accept the expert evidence concerning the doubling times of tumours. It is submitted that to accept that the tumour was faster-growing than the Peer data range allows, would require the Court to accept a speed of growth of the cancer “outside all sensible ranges contained in the known data.”

7.4 The Defendant replies that numerous characteristics mark this as a very rapidly growing cancer and this fact of very rapid growth, taken together with a bias towards slower growth in the data relied upon in the Peer paper, mean that the Plaintiff cannot rely on doubling time to establish that her cancer was detectable in May.

7.5 Further, the Defendant says that, while the tumour seen in October did start in the same quadrant of the breast, it was not in the same location as the pea-sized lump in May, which was most likely a simple cyst, as reported by the radiologist. They say this is supported by the appearance of the entity in October which would have been an obvious cancer 5 months earlier and not something that would be mistaken for a cyst. And finally, in this regard, the Court was told that cysts are an entirely normal occurrence in the breast and that there was no coincidence, but a tumour in a quadrant of the breast where there were also a number of cysts. Only the tumour is the unusual feature as cysts are very common.

8. Witnesses of Fact for the Defence

8.1 Mr. Sugrue and Dr. Mac A’Bhaird both gave evidence at length and, as is always the case in a medical negligence claim, their evidence falls to be determined as witnesses of fact, albeit witnesses with particularly relevant expertise in relation to oncology. The experts called by both sides in this case gave the most significant evidence in terms of the issues to be decided but these issues did not occur in a vacuum and, insofar as it is necessary to comment, the Court viewed both these defence witnesses as experienced doctors and reliable witnesses as to fact.

8.2 Both were somewhat defensive under cross-examination but no more so than might be expected; this is a normal, human response to being cross-examined in circumstances where one is being accused of negligence. There was close cross-examination of Mr. Sugrue in respect of his CV, which had no bearing on the case other than to confirm a long and excellent history in treating patients and training medical doctors. There was reference to the death of a former patient which, again, had no relevance to the issues in controversy here.

8.3 There was some cross-examination of Dr Mac A'Bhaird on an image which showed only a partial entity in the marked area of the breast, but which had all the characteristics of a cyst. He suggested that this may be an image of part of the 12mm cyst mentioned in his report but was not obdurate in this regard. His answers, generally, gave the impression of a witness trying to be helpful and not seeking to mislead. He was clearly very experienced and frankly acknowledged that, if there was a 15mm or a 12mm cancer present in the marked area in May, in his words, it would have been "substandard" not to find it. He was surprised, on reviewing the records, to discover that he had not taken an image of the largest cyst found. He was confident that he had not missed such an entity but that the cysts in the marked area constituted the pea-sized and peppercorn lumps felt by the Plaintiff.

9. The Peer Paper: Cancer and growth estimates

9.1 The question of whether one can estimate the size of a tumour at any earlier point in time often arises in the medico-legal context but is rarely an issue in the clinical setting, where the main focus is on treatment rather than the history of an individual cancerous growth. Nonetheless, the issue of rates of growth is important in both settings as, in the legal context, it bears on the question of whether one can determine that a cancer should have been detected and, in the medical context, it bears on the important question of screening intervals.

9.2 The Plaintiff's clinical expert relied on the academic paper, "Age-Dependent Growth Rate of Primary Cancers", to estimate the probable size of her cancer in May, given its volume in October. Published in 1993, the paper was written by Dr. Petronella Peer and a group of colleagues and was referred to throughout this case as the Peer paper or Peer et al. This paper has been used for decades in medico-legal contexts to determine the likely doubling time of breast cancer and to estimate the size of a tumour at given points in time. The reliability of the data in that paper for the purpose of estimating tumour sizes in a particular case was strongly contested.

9.3 The measurements taken in the data analysed by Peer and her colleagues were of 289 tumours diagnosed by mammogram in a screening programme, where earlier mammograms were available to be examined and where a shadow nucleus could be identified in hindsight. In other words, tumours which had not been detected until seen in a later scan at which point the smaller entity could be discerned, knowing where to look. The data included only those tumours where there were two images at different points in time. The growth rate was noted in each case and the mean and average growth rates for the group of women involved were identified.

9.4 The rate of growth for the purposes of the paper was expressed in the time taken for each tumour to double in volume (not just in diameter) across the two measured points in time. This led to the phrase "doubling time", sometimes referred to simply as DT, being used in this context.

9.5 The volume of a tumour is assumed to be comparable to that of an obloid sphere, which is determined by a mathematical formula, calculated using the diameter of the sphere. The practice of using the obloid sphere, and the mathematical calculations required to calculate the volume of this shape, were not put in issue in the case, other than to note that a cancer is not a perfect obloid sphere so there will be a certain, relatively minor inaccuracy in estimating the size of what is usually an irregular entity.

9.6 The further assumption made by the authors of the paper was that tumours, in general, grow exponentially. Again, this is a mathematical concept which requires some exploration. The basis for most of the academic papers in this field of study is an assumption that tumours follow a set pattern in the way they grow. If this pattern can be identified, one can estimate the growth rate of a tumour once one has two different measurements, or more, of that tumour at different points in time.

9.7 If one only has two points on a scale and is seeking to predict a future point on that scale or estimate an earlier point, it is a relatively easy task if the two points are simply points on a straight line. If the scale is not straight or linear but is a curve, then one must factor in the expected variation in the curve. At the time of writing in 1993, the authors in Peer's paper assumed that the growth of cancer followed an exponential curve, which veers upwards steeply. Since then, it has been relatively widely, though not universally, accepted that the growth of cancer follows a Gompertzian curve. This is a type of growth curve which has been identified in natural phenomena and it rises steeply before levelling off at larger sizes. It also features uneven growth periods. Peer et al accept in their paper that the Gompertzian model of growth was more likely to mirror the growth of breast cancer than their assumed exponential model.

9.8 It is obvious that there would not usually be two measurements of a tumour available as, once a cancer is detected, it is treated rather than monitored in order to collect statistics. Further, women whose cancers were not visible on an earlier mammogram could not be included in the data used in Peer's paper: there was nothing to measure, nothing to compare and no way to estimate the growth rate. In other words, women whose cancer grew between one scan and the next, often referred to as interval cancers, were not included in Peer's data. There were no very early-stage tumours included in the data generally, by definition, as they were too small to be detected in the first scan. This has the effect of skewing the data to some extent, which is acknowledged by the authors in the paper itself. The fastest growing cancers

were probably not represented in the average or in the mean numbers identified by Peer and there is no way of estimating the effect of this bias with any accuracy.

9.9 The objective of Dr. Peer and her colleagues was to investigate the effectiveness of screening for women on the basis that the data (of those cancers that could be measured) showed a median growth rate that was faster for women under 50, and sometimes significantly so. They recommended more frequent screening as a result of their findings. They were not attempting to construct a reliable method by which to estimate individual tumour sizes in a particular case. The data revealed growth rates between two points in time, at both of which times the tumours were detectable. In women under the age of 50, the DT tends to be faster and thus at the lowest number in the range of “doubling times”. In Peer’s data, the range was from 44 to 147 days. In other words, the woman whose cancer grew fastest of this group of 289 had a DT of 44 days, the slowest time noted for a cancer to double in volume was 147 days.

9.10 In 2005, Madeleine Tilanus-Linthorst and a team of Dutch medics published an article called “Hereditary breast cancer growth rates and its impact on screening policy”. While based on a much smaller set of data, 55 cases, the authors did correct for faster-growing cancers. The authors studied mammogram and MRI results in order to estimate factors which had an effect on growth rates. Again, as the title makes clear, their purpose was to inform screening policy.

9.11 At page 1615 - 1616 of the article, published in volume 41 of the European Journal of Cancer, the authors record that they assigned a value of <4mm (less than 4 millimetres) to the few cancers in respect of which they had only one image to ensure that faster growing cancers were represented in the figures.

9.12 In their conclusions, Tilanus-Linthorst et al appear to have recorded somewhat faster doubling times than those recorded in the 289 cases studied by Peer et al. In the abstract at the outset of the article, these authors record that the mean in carriers of a particular gene mutation was only 45 days (this was just above the lowest recorded

DT of the range noted by Peer, 44 days, with a mean DT of 80 days) and one of their conclusions was that age was one of the key determinants in the way the disease spread: the younger the women, the faster their cancers grew.

9.13 At page 1616 the authors refer to a paper by Spratt, in which a wide range of doubling times was found, ranging from 10 to 7051 days in women aged from 18 to 80. On the same page, Tilanus-Linthorst et al conclude that “[G]rowth may not be continuous and possibly speed up or slow down under influence of host factors or size.”

9.14 The last article discussed during the evidence is the Bhattarai article, “Machine learning-based prediction of breast cancer growth rate in vivo”. These authors examined mammograms taken from 114 patients between 50 and 70 years of age and selected those in which at least two images of each tumour, at an earlier screening and later at diagnosis, could be identified and measured so that the growth rate in individual cases could be recorded. The authors then used algorithms to identify the ideal model to calculate the rate of growth of in vivo cancer, in other words, cancer as it grows in the human body and not in a petri dish, as one witness put it. They created a surrogate model to test their results on an independent cohort of 1214 patients and found a high correlation between predicted and actual growth rates, suggesting that their predictive model was effective.

9.15 At page 502, the authors note that they found considerable variance in growth rates of tumours in the early stages and that their findings were consistent with a study by Weedon-Fekjær (published in 2008) who found that the time it takes breast cancer (BC) to grow from 10mm to 20mm in diameter varies from under 1.2 months to over 6.3 years. In the final paragraph, Bhattarai and her colleagues conclude that:

“multiple factors control BC growth. When considered together, Ki67, mitotic index and tumour size produce a robust prediction model of pre-diagnostic growth rate and can be used to classify BCs as slow growing or fast growing. The impact of missing

subtle cancers in screening mammography seems to depend on whether the tumour was slow growing or fast growing prior to diagnosis, as fast growing tumours were associated with poorer outcomes and perhaps reflected more aggressive tumour biology. Independent validation of these findings in multiple and more diverse cohorts is warranted."

9.16 The authors in Bhattarai refer to the Peer paper as one of a number of papers in which the authors considered fewer variables than were considered in the Bhattarai paper. The variables associated with growth rates include age, grade, HER2 status and ER status (the presence or absence of estragon receptors). Bhattarai et al also considered various possible growth patterns (earlier authors picked one growth curve rather than considering multiple options). In this paper, exponential and Gompertzian growth curves were considered as potentially appropriate predictors in constructing their prognostic model.

9.17 These papers make it clear that the science of estimating growth rates of cancer in the human body is imprecise and very complex and that our understanding of the factors that affect growth rates is increasing as is the sophistication of methods of prediction. None of the authors appear to express great confidence in estimating exact tumour sizes based on one reading and the application of a calculated growth rate.

10. Expert Evidence

10.1 Only one expert is permitted to give evidence in respect of a particular field of expertise to avoid an unnecessary proliferation of evidence and of experts. One aspect of this case that appeared to trespass on this important procedural rule was that all the expert witnesses had taken part in multi-disciplinary teams for many years. In this context, each was frequently asked about subjects which were, more appropriately, issues for another witness but about which they had long years of general knowledge. The same rule applies in respect of the witnesses as to fact, two of whom were highly qualified in the fields of clinical and radiological medicine

respectively. Any findings in relation to the conflict between the experts in this case do not rely on evidence from the witnesses as to fact other than to examine the factual context with which the experts' theories must be consistent in order to be persuasive.

10.2 Insofar as possible, the Court has restricted each expert to his or her area of expertise and relies only on the relevant witness. To do otherwise affects the quality of the evidence and its reliability, as it would emanate from a person with less subject matter expertise who collected the specialised knowledge in a general and collateral way, albeit at a high level and in a professional capacity. To rely on evidence from a witness other than the proffered expert would also jettison a procedural rule which exists not only to ensure that the Court acts on the best evidence but also to provide a reasonable and predictable structure for the litigant in this and in all similar cases.

10.3 Three expert witnesses gave evidence for the Plaintiff, each focusing on a different aspect of the triple assessment process. The first was Professor Nigel Bundred, the clinical expert, the second was Dr. Steven Allen, the radiologist and the third was Professor Ian Ellis, the pathologist. All three were highly qualified, all three had significant clinical experience, all had published extensively in their field and all had given evidence in medico-legal cases although Dr Allen had only done so once before. Each of the experts provided a report for the Court and then gave evidence on his or her area of speciality. It was relatively late in the case when the issue of doubling time crystallised as one that was both contentious and crucial.

10.4 The Plaintiff bears the burden of proof and the doubling time theory must be considered in the context of the facts of this case. This means assessing its reliability generally and whether or not it has been applied correctly in the circumstances of the case. The Court can only reach conclusions based on the evidence produced to support each side of the case and must also consider the weight to be attached to the relevant witnesses' evidence, particularly when the crux of the case depends, as it does here, on which of two expert witnesses is to be preferred: they cannot both be correct.

10.5 One complicating factor in this case was that the true picture of the defence case only emerged clearly when the Defendant's expert on doubling time gave evidence. His report, while generally critical of the data used by the Plaintiff's expert, did not outline the basis for his objections in any detail although this was much clearer by the end of his testimony. In circumstances where he was then cross-examined and no application was made to recall the Plaintiff's expert, the Court must deal with the evidence as it has emerged.

A.i The Clinical Expert for the Plaintiff

10.6 Professor Nigel Bundred was the clinical expert for the Plaintiff and his reports were dated 27th June 2020 and April of 2022, the latter containing more detailed references to the medical records.

10.7 The witness is a Professor of Surgical Oncology and Consultant Surgeon based at the University Hospital of South Manchester NHS Foundation Trust and the Christie Hospital in Manchester. He joined the University of Manchester as a Senior Lecturer in Surgical Oncology in 1991 and was appointed as Professor of Surgical Oncology in 1991. He has been the Greater Manchester and Cheshire Cancer Research Network Clinical R&D Lead since 2007, and Director of the North-West Surgical Trials Centre since 2013. He has been a member of various committees particular to breast cancer. He served on the editorial board of the British Journal of Surgery and has over 200 peer-reviewed publications covering breast cancer management and laboratory and clinically-based breast research, endocrine surgery, and endocrine cancer.

10.8 Professor Bundred's reports referred to the Peer paper as being a standard reference for doctors in this field and this was the data used in his calculations. According to Professor Bundred, using the Peer data and considering

the characteristics of the Plaintiff's cancer, a 15mm cancer was present and ought to have been detected in the Plaintiff's right breast on the 4th of May 2017.

10.9 What is immediately notable about his calculation, is that the size of the cancer as predicted by the Peer data, is the exact size of the lump palpated by Mr Sugrue in May. In light of this evidence, the Plaintiff submits, it is not credible to suggest that the Plaintiff was found to have an 'interval cancer' on the 9th of October, one that grew aggressively after the prior exam in May and was thus a cancer appearing in the interval between one appointment and the next. If the tumour in October was an interval cancer, there was no detectable cancerous lump in May and the pea-sized lump was a cyst. If the science of estimating growth is reliable, however, this could provide sound evidence as to what that lump was.

10.10 Professor Bundred indicated, based on the figures in the Peer paper, that the likely range in terms of DT for a cancer of this sort is between 44 and 147 days, and that the Plaintiff's cancer would have been at the fast end of this range. The more rapid the DT, the smaller the tumour would have been on the day of the alleged misdiagnosis (4th May 2017) but the Court is urged not to go beyond the doubling time rates identified by Peer et al.

10.11 Professor Bundred selected a DT of 45 days, from the wide range of doubling times available. He calculated, using the 45-day DT, from measurements of 34mm and 11mm in a bi-lobed tumour in October, that on 4th May, 2017 the pea and peppercorn lumps palpated by the Plaintiff would have been 15mm and 5mm and further, going back to 31st March 2017, that the same two lumps when she first discovered them, were 13 millimetres and 4 millimetres. He told the Court that anything above one centimetre was palpable by a clinician or G.P. He also gave compelling evidence that, in certain circumstances, a lump as small as 5mm (about the size of a peppercorn) could also be palpated if it was hard or granular and particularly if at the periphery of the breast, right under the skin. This was in line

with Mr Sugrue's evidence as to the importance of texture and firmness in identifying whether a lump was a cyst or something more sinister.

10.12 The Peer paper, Professor Bundred explained, had been backed up by subsequent literature, including the Bhattarai article of 2011. In addition, he referred to the Tilanus-Linthorst article saying that it showed a similar mean doubling time in women for breast cancer, which was 75 days, compared with the 80-day mean DT in Peer. As noted above, the mean DT for women with a particular gene mutation was lower again, at 45 days. Having noted that the mean in the Tilanus-Linthorst results coincides closely with that in Peer, Professor Bundred suggested that the noted size of the largest entity observed in May is the size that he would predict using this data and selecting the DT of 45 days.

10.13 He expressed the view, when cross-examined about Professor Crown's statement that the Bhattarai paper was more up to date, that "*Bhattarai is of no relevance to this case because it is not HER2-positive patients*". He also referred to the small number of patients whose data were used in Bhattarai, though he did not refer to the larger cohort against which the surrogate model was tested.

10.14 His verbatim evidence was: "*But, look, I'll be honest, tumour doubling time you can only estimate roughly where it would be. It wasn't 80 days, it's faster growing than that and everything about it says it's faster growing than that. Whether it's 45, whether it was 50, whether it was 60, it's about between 15 and 19mm in size.*"

10.15 In addressing Gompertzian growth, Prof Bundred explained: "*what Gompertzian means is that at the beginning growth is actually quite slow but then goes up pretty fast and consistently the same speed as you can see in the fast growing cancers... you will see for the fastest ten per cent within six months you are getting this very fast growth rate. And so the Gompertzian argument doesn't knock out any of that because she is on this bit of the curve where it is very fast growing. She is not on the bit of a curve in a slow*

growing patient where the speed of the growth is slowing down with time, she is on the fast growing bit. So I don't think it makes any difference to the argument."

10.16 The other evidence, from Professor Crown and from the articles handed into Court, suggests that the growth of tumours in the human body is not initially slow, is not consistent in speed, though two different curves may be consistent for part of their cycle, and that growth depends on a number of variable factors.

10.17 Professor Bundred's evidence went on as follows:

Q: ... the period of time we are talking about here is between May and October?

A: Yes.

Q: When there was a palpable lump in May. So we are obviously not in the very first days of the cancer?

A: It can't be on the flat bit of the curve because she can already feel the lump.

10.18 As is clear from this excerpt, from his reports, and from multiple answers in cross-examination, where reference is also made to the lump in these terms, Professor Bundred's calculations as to doubling time are based not only on the Peer paper data but on his theory that the pea-sized lump felt in May was the same as the tumour in October. The defence argue that these are different entities. This line of defence was clear from the pleadings, in which the lump is described as having been a cyst. If Peer's data alone cannot identify the previous size of this tumour, or not with any accuracy, the estimate of 15mm is not reliable. If there is no assumption about what was palpated in May, we are left with only one measurement, that taken in October, no indication as to when the lump formed, and no way of telling where on the growth curve this cancer was at any given time.

10.19 This argument is more fundamental than being a comment on where the tumour might be on a growth curve: if the size of the pea-sized lump in May has

informed Professor Bundred's thinking, then it is not just the reliability of the data in Peer that is in issue but there is strong evidence of a confirmation bias that the size of the cancer in May must have been 15mm as only this size lump will fit with the facts as to what was palpated and his theory that the lump was cancerous.

10.20 The Plaintiff submitted that Professor Bundred's approach was in accordance with the approach accepted in *Freeney v. HSE* [2020] IEHC 286, where reliance on the Peer paper was also made by the expert witnesses in that case, Professor O'Reilly. Hyland J. said at paragraph 191:

"The science of tumour doubling is a medico-legal construct and, as described by Professor Ellis and other witnesses, is not used in the practice of medicine. Two scientific papers were referred to in these proceedings, one by Peer and one by Michaelson, both of which ... allowed an estimate (varying depending on age) as to how fast an average tumour would grow over an identified period of time. All witnesses accepted that these rates were averages only and that individual tumours might differ from the norm. Professor Ellis proposed a confidence interval of 10% plus or minus in the result arrived from applying tumour doubling times."

10.21 After commenting on the defence experts' reluctance to rely on doubling time, in paragraph 208, Hyland J. continued:

"... they are generic statements based on moderate numbers of patients and they do not calculate a specific response in individual patients. Therefore, their application to an individual case is imprecise and unreliable. However, it is also the case that Professor O'Reilly said he would have accepted that the tumour was between 37mm to 40mm ... on the basis of tumour doubling time, were it not for the way in which the tumour behaved during chemotherapy which led him to believe there were fast growing aspects of it. I am therefore going to permit reliance upon tumour doubling times, while conscious of the imprecision of this method of estimation."

The position in the *Freeney* case was quite different, as this excerpt makes clear. In *Freeney*, there were experts who agreed, broadly speaking, that the doubling time rates as set out in Peer could be relied upon as averages, subject to the caveat that they are imprecise. There was even a range identified as to what size the tumour probably was but, again, with some caveats and one expert noting his reason for dissension.

10.22 In this case, the use of the method was vigorously disputed. In those circumstances, it is not open to the Court to adopt the method without further examination of the arguments, no matter how commonly used. The points made by the defence expert must be considered and addressed, even if his views were only expressed with clarity late in the case, in his oral evidence.

10.23 As noted, Professor Bundred placed reliance on the Peer paper data, also pointing to two later papers which, he said, supported these results. His evidence was that, with a young patient and with the features of her tumour, including that it was HER2-positive and ER / PR negative, the doubling time was likely to be very fast; of the available periods observed in the data set out in the Peer paper, Professor Bundred gave evidence that he chose a DT of 45 on this basis, because it is likely to have been such a fast-growing cancer. It was not the fastest DT observed by Peer (that was 44) nor was it the fastest in the literature produced (which appears to be as fast as 10 days, albeit that the patient may have been as young as 18: this was Spratt's article, which was referred to in Tilanus-Linthorst and was not provided to the Court).

10.24 Having noted that the Professor appeared to link the lump in May with the cancer in October, looking at the doubling time he had selected, it is highly likely that he chose 45 days DT as it gave exactly the result that he expected, having assumed that the lump in May was cancer. This was referred to by the defence expert as the Goldilocks phenomenon, the timing cannot be too fast or too slow, it

has to be just right. But this is only if you are matching the timing to the size of the lump in May. This is an assumption that the Court cannot make. Once this factor is eliminated, which it must be to consider the reliability of the Peer data for estimating the size of a tumour, it is clear that this cancer could have been faster, or slower, depending on variable factors, including where the tumour was on the growth curve and all the factors outlined in the Bhattarai paper.

10.25 Indeed, Professor Bundred did accept under cross-examination that the growth of the tumour may have been faster than was identified in Peer (when he was reminded that the women in question were in a screening programme) but as to the likely size of the tumour in May, he held to the view that it was 15mm though he later switched to 5mm, but here, he appeared to be guided again by the size of the lumps felt by the Plaintiff in May, the first of which was identified as a pea-sized lump and the second lump, which was the size of a peppercorn, or 5mm.

A.i The Clinical Expert for the Defendant

10.26 Professor Crown is a Consultant Medical Oncologist at St. Vincent's University Hospital. He sits as Newman Clinical Research Professor in University College Dublin and is the Chair in Translational Cancer Research in Dublin City University. Professor Crown has chaired or co-chaired up to nine breast-related clinical trials and has hundreds of relevant publications to his name. In his early career he worked in Sloan Kettering Hospital in New York, where thousands of cancer patients were treated annually.

10.27 Professor Crown gave evidence, for the defence, on the issue of doubling time. His first report, dated April 2022, did not refer to rates of growth but was relevant to quantum. A supplemental, undated report was delivered to the defence on the 3rd day of the hearing, 17th May 2022, and this was the first time that

Professor Bundred saw the defence response to his report, and specifically the response to his estimate of a 45-day DT for the Plaintiff's cancer.

10.28 At the start of Professor Crown's evidence, Professor Bundred's theory as to doubling time was put to him, to which Professor Crown replied that he thought Professor Bundred was not correct and that the theory had its basis in weak science and logic. Professor Crown told the Court that while in Sloan Kettering he had worked with Dr. Larry Norton, who was a mathematician as well as a medical doctor, and the witness's work included studies on the rate of growth in cancerous tumours.

10.29 It was specifically put to Professor Crown that he was not an expert in the topic of the rate of tumour growth. The witness replied that it was not an aspect of practice that came up in the clinic but that he had studied, for over 7 years, with an expert in the field. The specific study of doubling times was one in which he had engaged at great length and it remained an issue of interest to him and one on which he had firm and clearly expressed views. For four years of his clinical practice in breast cancer he designed clinical trials, nationally and internationally, including trials based on doubling time. The witness appeared to the Court to have considered the issue at greater length and in greater depth than the other expert witness, Professor Bundred, who was asked to address the topic in this trial.

10.30 Given the references to the *Freeney* case throughout the trial, it is necessary to note that this witness also appeared to have greater expertise in this field than any witness who gave evidence in *Freeney*. There, Hyland J. relied on the Peer paper but set out her reservations in that regard and drew attention to the fact that she did not have the evidence of an expert in that particular area of academic and clinical practice. Professor Ellis was co-author of a relevant article but was not called as the expert on doubling time. Although the Court will nonetheless describe his views, they cannot be relied upon in this context as he was

not the expert relied upon. Counsel for the Plaintiff accepted this, noting that they had asked for his views simply because Professor Crown referred to his paper. Professor Ellis was not cross-examined on doubling time.

10.31 Professor Crown's answer as to his expertise in this field was not challenged. Professor Crown's evidence on this issue was, therefore, crucial. He had been asked many times to give evidence defending in medico-legal cases and, he explained, in most cases he wrote back indicating that he considered that the practice outlined in the notes he had seen was negligent. It would be unusual, he said, for him to contest a plaintiff's claim of negligence, considering the requests he had received over the years. This was the first time he had given evidence in a court case. My impression was that he agreed to give evidence in this case because he was concerned that the concept of doubling time was being relied on to make findings of fact that were not adequately supported. This may also explain why the very clear evidence he gave in person was not reflected in his report.

10.32 The first issue addressed by this witness was the antiquity of the Peer paper and the inadequacy of using mammograms, the only method of imaging examined by the authors. Not only was there better technology available now but, as he pointed out repeatedly, the authors created the paper to improve screening programmes and never purported to offer a method of measuring growth rates in individual cancers. The authors themselves, in the paper, acknowledged that the growth rate curves used, exponential curves, were the wrong model to use. He explained that while cancers in petri dishes aligned with exponential growth curves, in human tissue, the cells behaved differently. Gompertzian growth was the more likely pattern of growth in cancers in the human body, in his view.

10.33 In explaining this phenomenon, the witness said: *"it is widely, widely understood that implicit in Gompertzian growth is the discontinuous nature of the growth*

rate. It is not a continuous growth rate and it is at its greatest when the tumours are very, very small and it does tend to level off as the tumours get bigger."

10.34 Professor Crown also told the Court that recent research suggests that growth rates in cancer are better understood by examining more than one Gompertzian curve. A more useful model is to look at families of Gompertzian curves, as this model reflects the heterogenous nature of cancer, employs different rates of growth at different times and for different types of cancer in different environments. He also explained that the study of the variables that might affect the growth rate in cancer is usually forward looking in oncology, in other words, looking at what happened to the tumour in the past is not as useful as predicting how it will respond to treatment. This is why there is much less research into how variables affect early growth in tumours.

10.35 A significant feature of this witness's evidence appeared under cross-examination, at day 21 of the hearing:

"...virtually all of the literature quoted, by which theoretical or notional doubling time constructs have been developed ... revolved around cases where there were two measurable time points on radiology imaging, which meant that there was some type of image marked X, some type of image marked Y, [and the question asked] how much growth was there between them? Get out the ruler, get out the calculator, get out your watch and work out what the doubling time is... But all of those studies are also biased by the fact that they were the kind of cancers that did show on two imaging studies at appropriate time point[s], and ... in the Peer paper, the range of doubling times that they quote does not allow for the fact that there might have been some cancers which grew so quickly that they in fact could not have contributed to that dataset because they would not have been in a previous mammogram. That's the problem.

So, again, I'm not trying to trivialise this. There's a kind of Goldilocks phenomenon here. The doubling time can't be too fast, it can't be too slow, it has to be just right. And that's what I'm troubled by in this. I do not believe it is possible to say what the doubling time was in an individual cancer, and I believe the confident assertion made in one of the other submitted reports that the doubling time was X and as a result the tumour was Y and as a result the likelihood of lymph nodes was Z is just not correct. I think it is wrong."

10.36 Professor Crown pointed out that because many cancers grow at a particular rate once identified tells us little about the rate of growth before they are large enough to appear during breast imaging or to be felt by the patient herself or by a clinician. While one could speculate as to where any given tumour is on a growth curve it is only speculation. One can only say that, once detectable, it is no longer on the lowest point of the curve. As regards this tumour in October or any detectable tumour, as the witness put it, *"if you look at either Gompertzian or even exponential growth, it's quite high up the curve. There's an awful lot of the natural history of the cancer before it becomes detectable to any technology"*.

10.37 The witness was cross-examined on the point that heterogeneity can give rise to an unreliability in growth rates but that the Plaintiff's cancer appeared to be homogenous, to use the word put to the witness, suggesting that her cancer might behave more predictably. Professor Crown explained that just because the Plaintiff's cancer was HER2-positive, ER / PR negative and the signs after treatment were that there was no HER2-negative or oestrogen receptor positive elements to the tumour did not mean that the tumour was homogenous. The witness rejected this analysis pointing out that cancer is a complex phenomenon or, in his words, it is *"extremely likely that there were multiple subclones within that tumour that had diverse phenotypes and, as such, would be evidence for heterogeneity. Thankfully, none ... was resistant to the treatment that she had"*.

10.38 Professor Crown disputed the growth rate being used by the Plaintiff's witnesses specifically due to the underlying reliance being placed on the Peer paper. He found no support for Peer's position (as articulated to ground the Plaintiff's estimate of doubling time) in the Tilanus-Linthorst paper. Again, he concluded, the problem was that, within a range of cancers which are detectable with the growth rates that were observed, there may be some cancers which grew more quickly, which entities would not have been apparent at all on the first mammogram or the first MRI and, as a result, a bias is built into the dataset which was set out in the paper and which was then imported into this Plaintiff's case. In respect of the authors of the papers, I did not understand the witness to criticise the authors but he was highly critical of the evolution of the data in the Peer paper into a kind of scale for estimating tumour size which masks the complexity of how cancer grows.

10.39 It is important to note here that, in examining the literature, it appeared to the Court that Tilanus-Linthorst and her colleagues did propose a correction to their data for faster growing tumours by factoring in a notional size, as set out in the opening section of their paper. Thus, the same argument has less force when considering the Tilanus-Linthorst paper but the data range relied on was that in Peer and not in any of the later papers. Further, it was not proposed that the Court rely on a range of possible doubling times, including those identified by Tilanus-Linthorst some of which may well have been lower than those in the Peer data given the mean of 75 days. The Plaintiff's case rested on one specific DT taken from the Peer data which, as it happens, is the only one which would lead to a result consistent with the Plaintiff's case theory.

10.40 In a more general way, as Professor Crown emphasised, to repeatedly rely on the Peer paper as a rough guide to doubling times led to the phenomenon whereby the paper became much cited and thus created the impression that it was more reliable for identifying tumour size than it actually is.

10.41 Professor Crown's evidence was that, because we have no idea when the October tumour first appeared or the exact rate at which it grew, there is no way of identifying, precisely, what size it was in May. His expertise as to the nature of tumours led him to accept that cancer was present in May, but he did not accept that the size of any tumour could be estimated from information about the dimensions of a tumour in October. There is no way of identifying where on the curve this October entity was located, even leaving aside the question of which curve is the most appropriate to try to estimate its growth pattern.

10.42 The effect of the witness's evidence was that it was tenable on the academic information available to argue any of the following: (a) that the tumour was so fast-growing that it had not been detectable in May, (b) that its growth was so slow that its detection in October meant that it made little difference when it was detected as it was only marginally bigger than in May, or (c) that it was smaller and detectable in May, but had not been detected. His evidence makes it clear that these are all possible results looking at the data on growth rates alone and that it is speculation to prefer one over the others. He was of the view that the radiological evidence in this case tends against (b) and (c) and, in my view, the combined evidence as to what was observed in May (by the Plaintiff, the clinician and radiologist) makes (b) very unlikely.

10.43 One of his answers, explaining why this witness refused to accept that one figure from the Peer data could be used in the way proposed in this case, and giving his reflections on the other facts of the case was this:

"You're trying to get me to make a case for you as to what the size of the tumour was at a particular point in time and whether it should or should not have been detected. I'm not going to do that, because again the certainty which is built into these kinetic models is such that the doubling time might have been so frighteningly in theory, and I'm not saying this was the case might have been so frighteningly rapid that at the time

of the May presentation to the out patient clinic there was nothing there which could be felt or seen, and the only evidence we have on that is... the radiology reports both from Plaintiff and Defence experts that nothing was seen. So it is not a theoretical conjecture. It is something that has actually been stated and audited by your own radiologist that nothing was seen. So that's the problem we have. You're asking me to theorise in the face of the facts, and I don't know, there may have been a delayed diagnosis, there may not have been a delayed diagnosis. I'm not in a position to know that, and I'm not going to offer an opinion on it.

... I don't mean to trivialise this when I say the Goldilocks phenomenon, you know, if the growth rate is too rapid ... it undermines the case that something should have been seen in May, and if the growth rate is too slow, it undermines the case that it made any difference, and I don't where it was and nor I can know."

10.44 Addressing the report and the evidence of Professor Crown, the Plaintiff argued that the thrust of Professor Crown's report was not to suggest that there was no cancer, or an undetectable cancer, present in the Plaintiff's right breast in May 2017 but to go in the other direction and suggest that the cancer was more advanced than Professor Bundred suggests. In this regard, the Plaintiff argues that the Court must consider the penultimate paragraph of page 3 in Professor Crown's second report, where he states:

"In Gompertzian kinetics the growth rate of tumour levels off at larger sizes, thus an earlier brisk phrase of growth and Mrs. Crumlish's tumour would tend to slow down at larger sizes, providing a sound basis to believe that there may have been less change between May and October than would have been predicted by the earlier and now largely disbelieved exponential growth model".

10.45 The Plaintiff, in submissions, also drew attention to Professor Crown's statement that he was not in a position to say whether there had been a delayed diagnosis and that, while Professor Crown refused to regard doubling times as a

science he would become involved with, he did accept that the cancer was a fast growing cancer and that should undermine the opinion set out in his report.

10.46 The problem with this argument based on the line, quoted above, from his report, is that it ignores the thrust of the witness's evidence to the Court. While undoubtedly it must be considered, the opinion set out in his report was not refuted by his oral evidence but explained and in much more comprehensive terms. Professor Crown repeatedly emphasised the shortcomings of the Peer paper when used to predict tumour size: the exponential growth curve used (instead of the Gompertzian curve or family of curves), the availability of two measurable tumours in all cases involved in Peer's data and the fact that very fast-growing cancers could not be included in that early data as there was no first measurement, combined to make the witness very sceptical about the reliability of the data.

10.47 Professor Crown also, through the Goldilocks analogy, alerted the Court to the fact that the Plaintiff's expert was choosing the one doubling time that would lead to a result consistent with his theory. There was no detailed explanation as to why 45 days was chosen other than to say it was at the faster end of the range identified in Peer. It appears to the Court that confirmation bias accounts for the specific choice of 45 days in this case and, as Professor Bundred conceded, the rate could be as slow as 60 days. What Professor Bundred did not factor in, but what Professor Crown has persuaded the Court that it must consider, is the possibility of a faster doubling time than 45 days. If the doubling time was faster, the calculations of Professor Bundred, matching the size of the tumour to the size of the lump, are no longer reliable and the lump and the tumour were unrelated. There is nothing in Peer, or in the evidence presented to the Court, which suggests a specific doubling time for this case and there is no reason to select 45 days rather than any other doubling time, in a remarkably wide range even if we confine that range to fast-growing cancers. If the Plaintiff is to prove that the pea-sized lump

was cancer, the Peer paper, and Professor Bundred's evidence as to its effect, does not achieve the level of probability required to do so and an assessment of the other evidence is necessary in order to determine what the pea-sized lump was.

B. The Radiological Experts

10.48 Dr. Steven Allen, consultant radiologist for the Plaintiff, works as a consultant cancer imaging radiologist at the Royal Marsden Hospital and as a breast screening radiologist at the Southwest London Breast Screening Service and has done since 2006. Patients from all over the world are sent to this clinic which, as a result, can offer practitioners wide experience in many types of breast cancer.

10.49 Professor McNicholas is a consultant radiologist attached to the Mater University Hospital and she is also attached to the BreastCheck National Screening Programme. She gave evidence for the defence. The Professor has been a specialist in radiology for over 35 years. For the past 22 years she has been a consultant radiologist in the Mater Hospital and the National Breast Screening Programme. She has occasionally given evidence as she feels it is her duty to do so.

10.50 Dr. Allen agreed that courts tend to rely on the ultrasound report as being the nearest thing to being present at the investigation. Professor McNicholas agreed: radiologists *"come to a conclusion based on the live examination and that is what I would hang my hat on rather than the images they may or may not have provided."*

10.51 Dr. Allen said that the standard practice of capturing images is to show the largest view of the entity being pictured. He found it confusing that there was no image of the 12mm lesion reported by Dr. Mac A'Bhaird. He said that this was particularly confusing when there was a 15mm lump, described as S3, and a report of a 12mm entity in the same area.

10.52 When asked about growth rates in breast cancer, the witness said *"I'm probably on the edge of my expertise terms in terms of tumour doubling time"* and agreed with counsel that he wouldn't *"even go there at all"*. He referred to his colleagues Professors Bundred and Ellis as being the source of his information that the tumour must have been 15mm in May. He relied on this to assert that it must, therefore, have been visible and that it was negligent not to see it.

10.53 Dr Allen's report, confirmed in oral evidence, concluded with the words: *"I could argue that given its location, typical malignant appearance and the measurement that has been recommended of 15mm it was a breach of duty not to have visualised this at the earlier time point."* Note these words: *"the typical malignant appearance and measurement that has been recommended..."*. The measurement that has been recommended was 15mm, and was suggested by the Peer data, and recommended by Professor Bundred so this witness did not comment on how the doubling time was chosen, merely adopted it. If he was referring to the pea-sized lump, he would not need to mention that it was a recommended measurement. So, this witness was live to the difference between the two concepts. Having accepted that the tumour seen in October was 15mm in May, the witness is commenting that, although the radiologist clearly saw a 12mm cyst, as this is in his report, he did not see an obvious cancer of 15mm or anything like it.

B.i "Typical Malignant Appearance"

10.54 The reference to appearance in Dr. Allen's report was explored further in evidence. A cyst has a visibly smooth border all around the entity and has a dark interior. It is usually ovoid, though sometimes round. It is easy to identify on an ultrasound as it is filled with fluid which appears black on ultrasound imaging and this accounts for the dark interior on the ultrasound images. If the border is irregular or features bumps, this is not a cyst and usually denotes a tumour which

is growing or expanding into the tissue around it. If the interior is grey, it is not a simple cyst and may be a tumour. The witness confirmed that simple cysts do not become cancerous.

10.55 In his report, Dr. Allen expressed the view that *“a 15mm solid lesion should have been very easily visualised in this area of clinical S3 concern”* and, commenting on this in his evidence, said: *“Obviously the majority of breast cancers won’t change the way they appear over a five month time period, they would just grow in size... on the balance of probabilities, that will look like a 15mm smaller version of the subsequent cancer if you were to have scanned it in May. I cannot see how it would look like a cyst.”* [my emphasis] This fact, that there will be no change in the appearance of a tumour in 5 months, if the expert witness will forgive me, is not obvious at all. There was lengthy evidence and cross-examination on the similarities between cysts and non-cystic entities, and how a fast-growing cancer such as this could be missed, confused with, or hidden by a cyst.

10.56 Professor Ellis, the pathologist, who was careful to say that this was not his specific area of expertise, described all sorts of cysts that could mask a cancer. The import of his evidence was that even entities that looked like cysts could be cancerous and should be aspirated so as to rule out any such risk. From Dr Allen, however, it appears that (without comment on whether Professor Ellis is right in his views in relation to cysts and aspiration) in the case of this cancer which was identified and measured and in respect of which multiple images were available in October, the entity that Professor Bundred’s calculations suggest was present in May, namely a 15mm tumour, would have looked like a smaller version of the October cancer. This explains Dr Allen’s surprise that the radiologist did not even see it, let alone record it.

10.57 The picture painted by Dr Allen’s evidence was that while many cysts may not be readily identifiable, this tumour, had it been 15mm in May, would look

nothing like a cyst but would be an obvious cancer. He later added, under cross-examination, that he would expect a 15mm entity to be found quite easily in a 422g breast, at the periphery of the breast, as this lump was.

10.58 It is interesting to consider the very similar evidence of Dr. Mac A'Bhaird in this regard. He was asked about the appearance of tumours and simple cysts and replied:

"They're chalk and cheese. Basically a cyst... has no echoes internally. It is black throughout. Tumours are echogenic. They've got multiple echoes ... Their borders are ill defined and you can see projections of them going into the adjacent tissue. So they're quite easily, quite easily differentiated from cysts."

10.59 Professor McNicholas gave similar evidence so there is no controversy about this issue. Professor Bundred told the Court, when asked about Mr. Sugrue's classification of the lump as S3, that "[w]hen he classified it S3 he wasn't sure. The radiology really didn't contribute, other than to say it might well be a cyst but he didn't follow through and aspirate the cyst." If the evidence about the appearance of cysts and the appearance of this tumour is correct, however, and it comes from experts on both sides of the case, the entity which became the tumour in October did not look like a cyst at any time. The R2 rating suggests that nothing resembling a tumour was visible in the lower right quadrant of the Plaintiff's breast in May. Whatever the entity was, the 15mm pea-sized lump in May in respect of which the radiologist gave evidence that there was a 12mm cyst on ultrasound, but of which there is no image, was probably not the tumour that appeared at some point before October as the latter could not have been mistaken for a 15 or 12mm simple cyst 5 months earlier. To find otherwise is to reject the eye-witness evidence, effectively, of a radiologist who knew exactly what he was looking for, where it was in a small space, and who recorded his findings, taking images of some of the cysts he saw in that space.

C. The Pathological Expert

10.60 Professor Ellis is a Professor of Cancer Pathology at the University of Nottingham and an Honorary Consultant Histopathologist at Nottingham City Hospital. He has worked as a histopathologist for decades, held many relevant posts and chairmanships, set up the national training programme in breast pathology to support multi-disciplinary working in breast cancer screening in the UK, and is the author of hundreds of relevant publications. The focus of his research is the pathology of breast cancer and the assessment of its prognosis. He sits on the editorial board of five medical journals.

10.61 Professor Ellis accepted that Mr. Sugrue's normal practice in terms of examining, marking and measuring a lump was good practice. This witness agreed with counsel for the defence that breast lumps do not move, although they not only grow bigger, they can also seem to be in a different place if a different imaging tool is used or if the patient is in a different position e.g. sitting instead of lying down. The witness was impressive not only in terms of his credentials but in the way he delivered his evidence and responded to questions.

10.62 In respect of the possible mis-diagnosis in May, Professor Ellis concluded "*I believe on the balance of probability that had any of those cysts been aspirated at the time there would still have been a palpable mass.*" This means that the cysts were not simple cysts at all. This may simply have been a slip, but if it reflects his views, it cannot be correct. The cysts shown in the ultrasound images were described by all radiologists as simple cysts and no other witness suggested that any one of them would probably have been cancerous in May. To this extent, and if not just a slip of the tongue, the witness expressed a view contrary to that held by the radiologists and I prefer the view that the cysts seen in the images taken in May were correctly

identified as simple cysts. This is not only the view of the relevant experts, it makes more sense. His views on the entity recorded as a 12mm cyst are dealt with below.

10.63 In his direct evidence Professor Ellis confirmed that he agreed with Professor Bundred as to the growth rate of the tumour for the reasons that witness had set out. Professor Ellis was asked about doubling time because one of the papers referred to in Professor Crown's report as being more up to date than Peer's paper was the 2019 article by Bhattarai. This witness was a co-author of that paper. The rules of procedure require that each party offer evidence from one expert only in a particular field of expertise on a particular issue unless the Court, for special reason, permits an additional expert. There was no such application in this case. Here, the expert was Professor Bundred.

10.64 Professor Ellis's evidence regarding doubling times is set out here, however, lest there be a view that his opinion might have led to a different result in the case had the Court been entitled to rely upon it. Insofar as it went, it was unlikely to do so. There appeared to be fewer differences in opinion between Professor Crown and Professor Ellis than might have appeared at first blush. This is probably because Professor Crown's views were much more clearly articulated in evidence than they had been in his relevant report.

10.65 Professor Ellis stated that the most widely quoted publication is Peer et al, that their method is the most accurate way of predicting breast cancer growth, and he described it as having the best data available. He described using the same methodology, comparison of measurements of the same tumour to identify what affected growth rates in breast cancer, in his own research. His exact evidence was: *"It is impossible to say with absolute certainty what her tumour doubling time was. But I would advise it is somewhere between 44 and 80 and I would advise it is closer to 44 than it is to 80"*.

10.66 He also considered growth rates in breast cancer were more likely to be exponential while other cancers appear to follow Gompertzian models. This last comment is slightly problematic as Peer et al appeared to consider Gompertzian growth more likely, in line with Professor Crown's evidence. However, this witness was a co-author of the Bhattarai paper in which multiple variables and curves (including both exponential and Gompertzian) were analysed in conjunction with data taken from two different cohorts in order to try to better predict growth in tumours in vivo so it may be that his information and research as to which curve was appropriate was the most up to date. The issue does not appear to affect the conclusions in this case, in any event.

10.67 Professor Ellis gave evidence before Professor Crown. He knew that the Peer paper had been criticised in Professor Crown's report on the grounds that it was now quite dated but Professor Ellis's view was that, since neither human biology nor the biology of cancer had changed in the three decades since this paper was written and Peer and her co-authors had access to data from 289 women, this made the results statistically significant and they remained reliable data on which to estimate growth.

10.68 He also acknowledged that the Peer paper didn't "*deal with some of the nuances that we now understand with molecular sub-types but we understand those molecular sub-types very well, we know that ... triple negative and HER-2 have very, very high growth fractions and that is why they are important clinically.*" He was not asked about the bias against fast growing cancers in the data but, as is clear from the papers themselves, Peer et al did not factor in the possible bias but Tilanus-Linthorst in 2005, and Bhattarai and his colleagues (who included this witness) in 2019, attempted to do so.

10.69 Professor Ellis told the Court that the methodology used by Peer was sound in terms of predicting an average range of growth for certain types of breast

cancer, but that is not controversial. While Professor Crown's evidence has been characterised as an attack on the Peer paper, he was not critical of the authors or the data insofar as their work served a very important purpose at a time when the complexity of cancer growth was not as well understood as it is today.

10.70 I accept what Professor Crown says in relation to the more nuanced understanding of factors which affect growth and his point in this regard is not answered by simply saying, as Professor Ellis did, that cancer has not changed so the growth data in Peer is still reliable. In fact, Professor Ellis's own comments about nuance and the factors that are now understood to affect growth rates, which are clear from Bhattarai's paper, chimed well with Professor Crown's evidence. Professor Crown pointed out that the Peer paper was only reliable insofar as it measured particular types of cancer and its findings understood as average numbers. Professor Crown's view was that the authors would not, for the reasons he outlined, have confidence in using the data collected to estimate growth rates for cancer with only one measurable entity and for medico-legal purposes.

10.71 As for Professor Ellis's evidence as to the possible size of any tumour in the Plaintiff's breast in May of 2017, the full extent of it was to say it was more likely to be at the faster end of the Peer range. He did not align himself with Professor Bundred's specific choice of 45 days. Nor was he given an opportunity to consider the possibility of this tumour having a faster growth rate due to the bias identified in Peer's paper or the figures seen in more recent papers. Nor did he consider the risk of confirmation bias, namely that the 45-day rate was chosen as the best match for a lump that measured 15mm, not as the most likely rate. These matters were not put to him as he was not the relevant expert, there was no application that he give evidence on the issue and, as the witness agreed, he had not been retained to comment on doubling time nor did he do so in any report for the case.

10.72 Finally, neither he nor Professor Bundred offered any alternative view to the 45-day doubling time and the general tenor of their evidence was that this was a fast-growing tumour. The report of Professor Crown, which emphasised that the doubling time could not be known and could have been slower, may explain this emphasis on speed but failure to consider numbers outside the Peer data. This Court is satisfied that, on the evidence presented in this case, the only reliable way to use such statistical data is to consider a range of potential rates of growth. This can be narrowed down if the facts of the case include evidence to support a particular figure but that did not arise here. The most significant surrounding evidence of relevance was the radiology report, already assessed above, the estimated locations of the entity in May and the tumour in October and the Plaintiff's evidence, which are considered below. None of these separate pieces of evidence suggested any particular doubling time.

10.73 There was no evidence in this case addressing what the size of the cancer might have been if the doubling time was 44 days, 22 days, or even faster. Professor Bundred did not accept that it could have been faster than in the data outlined in Peer. If the tumour was, plausibly, even a few millimetres smaller than 15mm in May, then the doubling time estimate did not explain the lump in May, the smaller cancer was elsewhere in the breast and the lump was a cyst. The reliability of the chosen DT was a crucial element of the Plaintiff's case. Any faster doubling time reduces the size of what could be seen in May and a significantly faster time, which the more recent academic literature supports, would lead to a much smaller entity in May. The probability is that the doubling time was faster than 45 days and the tumour, which was there in May, was smaller than a pea-sized lump, which leads to the conclusion that the lump was probably a cyst.

11. The Clinical Experts

11.1 The role of the expert and the relevance of the expert's demeanour and approach to giving evidence has been considered recently by the Court of Appeal in *Patrick Duffy v. Brendan McGee & Anor*, [2022] IECA 254. Noonan J. delivered the judgment of the Court and Collins J. added a short judgment commenting on the position of the expert generally. The decision as to which expert opinion carries more weight remains with the Court, both the premises on which the opinion is based and the experts' evidence in general should be considered in deciding what weight to attach to the views of one or the other, with the decision on the evidence remaining one for the Court and not one that is ceded to the expert, no matter how well qualified.

(i) Assessment of the expert clinical witness for the Plaintiff

11.2 While all of the experts were eminent medics and most gave dispassionate evidence, the Plaintiff's case relies very heavily on the evidence of Professor Bundred. He was not as impressive as Professor Crown in his use of logic or in his approach to the case generally. The logic of the two arguments made has been explored above. To be fair to Professor Bundred, it must be repeated that the relevant report was only seen by him the day before he gave his evidence. Further, one of the arguments, that the pre-detectable tumour is not sufficiently represented in the range suggested by the Peer paper, was not as clear from the report as it was in oral evidence and from close study of the relevant papers that were handed into the Court. The other, that Professor Bundred was assuming a particular size of tumour in selecting a doubling time which matched his theory, was flagged in the report but more clearly spelled out in evidence.

11.3 Nonetheless, the facts relevant to the data are clear from the paper itself which confirms that it is confined to 289 women whose cancer, having been detected, could also be seen on a previous mammogram, and therefore measured. In the paper itself the authors acknowledge that there was no attempt to correct the figures to account for interval cancers and that therefore, there is a bias towards slower growing rates.

In this case, the expert witness took the data from these 289 women, chose the second fastest doubling time and nominated it as the most likely speed of growth in the Plaintiff's case.

11.4 The defence relies, in submissions, on the case of *Rossiter v. Donlon* [2019] IEHC 105 where the same witness gave evidence on doubling time but revised his central opinion between his first and second reports on both the tumour doubling size and the relevance of particular papers. The Defendant's submissions cite, in particular, para 381 of the judgment, where Barr J. noted that Professor Bundred: "*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.*" In fact, this might be consistent with relying on the papers in other appropriate cases, but the details recorded of his evidence rule that possibility out.

11.5 At paragraph 41, Barr J. records his note of the witness's evidence saying that he accepted that the Tilanus-Linthorst and Peer papers were the standard papers but that Peer was somewhat old and did not give much detail about the number of patients aged 32 years, or even those under 50 years. The note recorded that Professor Bundred said "*Peer et al. had nobody under 41 years. It was only a guide.*" This is a striking limitation on the Peer paper data that does not appear to have entered into the witness's calculations in dealing with the 35-year old woman at the centre of this case.

11.6 Professor Bundred's cross-examination began with some straightforward questions about Mr. Sugrue's normal practices: interview of the patient; measuring and marking lumps; dictating a letter in her presence of the patient. The expert witness's responses were not as one might expect. While Professor Bundred was not there in the clinic (or in the courtroom, he read the Plaintiff's evidence), he took the

view that Mr. Sugrue had not communicated well on the basis of a transcript of the evidence. He concluded that the Plaintiff was probably too intimidated to ask Mr. Sugrue for details or explanations. He referred to her account of the exchanges as “a closed conversation”. This was not my impression of her evidence. More significantly, the Plaintiff herself made no such complaint, then or since then, about Mr. Sugrue’s manner of communication during that first clinical examination.

11.7 Professor Bundred queried whether it could be true that Mr. Sugrue did not remember the consultation in May. As Mr. Sugrue maintained that he was not concerned about the Plaintiff in May, there was no reason to remember her visit at that time. Other expert witnesses, on both sides of the case, had no difficulty in accepting the proposition, confirmed by Mr. Sugrue and Dr. Mac A’Bhaird in evidence, that they had no memory of the Plaintiff’s attendance in May. This appeared to the Court to be a normal state of events in the professional lives of expert medics.

11.8 By the second day of cross-examination, the witness commenced his evidence with an introduction, taking about 10 pages of transcript, occasionally interrupted, to give a detailed explanation in respect of cysts, with references to articles which had not been provided to the defence. He then offered views on governance which, while they may have been relevant in other circumstances, were not raised on the pleadings in this case and were highly critical of the Defendant.

11.9 The process of managing a witness, whether by counsel or by a court, is more difficult when the witness is offered as an independent expert. One always offers some leeway to experts in the box, particularly when they are clear and helpful in respect of the subject matter of their expertise, as Professor Bundred often was. The problem was that the witness, without being improperly biased, was reviewing and interpreting matters for the Court, without any prompting by counsel, on the premise that the Plaintiff had a detectable cancer in May, which was a key matter of fact for the Court and not one that could be stated with the certainty he appeared to feel.

11.10 When Professor Bundred was asked about the NCCP guidelines which had been accepted as the relevant guidelines in Ireland at all material times, he said that he did not accept that they were relevant as they were breast screening guidelines rather than diagnostic guidelines for symptomatic patients. The guidelines are described as applying to symptomatic patients.

11.11 The witness went on to assert that Mr. Sugrue had never offered aspiration to this Plaintiff. This was a conclusion of fact for the Court and the witness appears to have simply accepted the Plaintiff's account in that regard. Mr Sugrue gave evidence that he would usually make that offer. There is no need to debate the honesty or reliability of this statement as it may well be true even if in this patient's case, it was not offered. The point is mentioned simply as a further illustration of the limits of the expert's role and the kind of evidence which may step over that line.

11.12 By the second day of cross-examination, the witness had put forward, for the first time, the thesis that measuring the exact location of any lump on the breast in this case was irrelevant as the tumour had, by October, caused so much internal distortion in the breast that measurements were irrelevant. This is interesting for two reasons: the first is that the original report makes no such comment but that often happens in evidence under cross-examination as issues are teased out properly. The second is that his case (and the Plaintiff's case) was that it was the same lump. If measurements were irrelevant and it mattered only that the lump was in the same quadrant, this makes his evidence all the more reliant on doubling time to justify a conclusion that the lumps were one and the same entity in May and in October. The Plaintiff relied heavily on the submission that the pea-sized lump was in the same location, not just the same quadrant, as the tumour.

11.13 The comments also render a few days of evidence unnecessary, if correct. All the other witnesses were examined and cross-examined, some at length, as to where the lump in October was found, what was its focal point, what was its likely origin

and whether it could be the same lump that was identified in May. Neither side appeared willing to abandon the view that the location of the lump and the tumour favoured their view of the case. The Court has commented further on this issue below, under the heading “Location of the tumour”.

11.14 By the end of a series of questions about location, it became clear that the witness was suggesting that the peppercorn sized lump, not felt by Mr. Sugrue, was the potential cancer that had been missed and not the pea-sized lump of 15mm. This evidence contradicts Professor Bundred’s own calculations based on the Peer paper, namely, that the cancerous tumour in October was already present in May and was probably 15mm. The peppercorn lump, to give it a neutral term, was one third that size. There was no attempt to marry this evidence to the Peer data. It is not consistent with the strongly expressed submission that Peer’s data, given a DT estimate of 45 days, leads to the inexorable conclusion that the tumour was 15mm in May.

11.15 The witness’s comments on some of the defence arguments which were put to him, were not just dismissive but verging on derisive. At one point he said that he was staggered at the information that the LUH clinic had won a patients’ award for excellence and asked for proof of this. Immediately afterwards he stated that the practice of dictating a letter in front of a patient was humiliating for her. As with the communication issue he raised, there had been no such evidence from the Plaintiff herself and the Court does not share this view as so much depends on the tone and manner in which this is done, none of which was in evidence or even put in issue.

11.16 In commenting on Professor’s Crown’s report, Professor Bundred used the terms “slap dash” and “completely crazy”. There were errors in that report in which a calculation is based using the whole of March, for instance. It was clear that Professor Crown had not factored in the date of first discovery, namely the 31st of March before the appointment in May. Equally, he referred to July as the month in which the Plaintiff felt a lump in her armpit. These may well have been factual errors

but, leaving aside the question of who made them or how the errors arose, neither one rendered the report or Professor Crown's evidence unreliable and what was in the report merited more than the contemptuous dismissal of the report as crazy.

11.17 There was less sense of balance from Professor Bundred than one would expect from a witness of his skill and experience, and little sense that the propositions being put to him were considered carefully before being rejected comprehensively, as so many of them were. Again, to be fair to this witness, it was clear that the third day was a physically demanding one for him. He had been more impressive in his direct evidence and was clearly a clinician of vast experience. The fact that this witness strayed outside his expertise to comment on communication styles and memory, the fact that he adopted a somewhat closed attitude, and that his answers in tone and, sometimes, in content, were intemperate, the fact that he contradicted himself, all of these factors, taken together, rendered his evidence less persuasive to the Court.

11.18 I do not believe that Professor Bundred deliberately sought to cast Mr. Sugrue as a liar but his espousal of the Plaintiff's case appeared sufficiently strong that he was inclined to be suspicious generally in respect of Mr. Sugrue, even where no suspicion was warranted.

11.19 My impression was that the witness had espoused the Plaintiff's case too closely. He offered evidence that was often accurate and even valuable but the weight of the evidence was affected by his cleaving to the Plaintiff's account and appearing to marry the Peer data to that account rather than considering doubling time as a science in isolation and in the light of possible alternatives offered by the defence. Again, it is only fair to comment here again that it would have been easier for this witness to comment on the evidence that was actually given than on the report, which was not as detailed or well-reasoned. As noted, that was not possible, but no application was made in that regard although submissions emphasised that the report

of Professor Crown appeared to anticipate that he would say that the tumour was slower to grow than Professor Bundred allowed.

11.20 As noted above, in a previous court case this witness rejected the reliability of the data in the paper on which he now seeks to rely in this Court on the basis of the age of the patients involved, but did not limit his reliance on it here. This, added to all the factors set out in this section, reduced the weight of his evidence considerably.

11.21 By way of contrast, Professor Crown was not on any side. He was quite prepared to criticise the Defendant and Mr. Sugrue but was sympathetic to the Plaintiff. He was at pains to emphasise that he was not giving evidence against her and did not question her sincerity. He explained that he was motivated to give evidence by what he considered to be a dangerous over-reliance on the Peer data to extrapolate what size individual tumours might be. He engaged readily with all questions in this regard. My criticism of him is confined to the quality of the original report which did not articulate the issues as clearly as he did in oral evidence.

11.22 The impression created by Professor Bundred was that he was on the side of the Plaintiff throughout the case. This is human, of course, and is exactly the phenomenon observed in most of the seminal cases on the role of the expert in litigation but is also the very attitude in respect of which expert witnesses should be wary and is the reason for the declaration of independence that they all sign.

(ii) Assessment of the Peer data and the surrounding evidence

i. The Peer data

11.23 The Peer data involves specific types of cancer at two precise points on a curve. In this case, the Court cannot assume that the lump palpated in May 2017 was a tumour, so there is only one point on this curve. There has been no evidence to justify the selection of 45 days as a likely doubling time other than to say that the Plaintiff's tumour was at the fast end of the range. The Court is not satisfied to

rely on Professor Bundred's evidence in this regard and prefers the evidence of Professor Crown for all the reasons set out, including the logic of the two positions.

11.24 The only measured entity that is relevant to doubling time is the tumour measured in October. Without any idea where on the curve this tumour was, it is more difficult to estimate the doubling time of the entity. That argument seems self-evident. But the problem with the Peer data goes further than this. As must be clear from the caveats attached to using that data to predict the size of a tumour at a given point in time, the figures are approximate only.

11.25 Further, the available figures all deal with tumours after they have become large enough to detect. There is no hard data about the growth rate of tumours that are undetectable in Peer's paper. This Plaintiff was suffering from a particularly aggressive and fast-growing cancer by every metric, including her age. The Plaintiff cannot show that her cancer had a doubling time of 45 days by reference to the Peer data alone. Her case rests on this figure and it is likely that this was chosen as only this doubling time that aligns closely enough with, and explains, the evidence of palpable lump of 15mm. The Court cannot make the assumption that the two entities are the same. If this cannot be assumed, the other evidence relevant to the issue of what was present in May must be assessed.

ii The surrounding facts

11.26 In May of 2017, Dr. Mac A'Bhaird probed the marked point on the breast where the lump was and found evidence of multiple cysts. The type of cancer found in October means that if it was already 15mm in May it was an obvious cancer. Wherever its location in the lower right quadrant, if it was indeed the same entity as the lump, that lump was peripheral and would have been very different in appearance from a cyst. The evidence establishes that if this entity was 15mm, it would probably have been obvious to the radiologist as it looked nothing like a cyst. If the 15mm lump was a cyst, this becomes a much easier case to explain.

11.27 The report of a radiologist was accepted as being the definitive description of what he saw, in normal circumstances. The only evidence that suggests that the radiologist missed a 15mm cancer is the evidence in relation to doubling time. If the range in the Peer data is not sufficiently reliable to estimate the size of what was present in May, then there is no evidence to support the proposition that the radiologist missed a 15mm cancer. It is unfortunate that the entity, although seen on screen, was not captured in an image but this does not appear to the Court to constitute negligence and every relevant witness agreed on this point. I do not ignore the evidence of the Plaintiff in this regard. While she could palpate a lump in May, nothing that she felt with her fingers can help the Court with identifying whether the lump was a tumour and this is considered further below.

11.28 In this case, a measurement difference of 5 millimetres or even less would make the difference between an entity being detectable or not, and in this case the facts include the Plaintiff's and Mr. Sugrue's evidence that the entity was about 15mm in May. Given those facts, one can see why it is unsafe to select only one of the doubling time rates in a study carried out by different means (mammograms) on cancer in women of various ages whose tumours were all detectable in both mammograms, in order to estimate the size of a HER2-positive, ER and PR negative, grade 3 tumour in a 35-year old woman in May, when it was 34mm on an ultrasound in October.

11.29 It is one thing to take a measurement of a lump in May, note that it is 15mm, and then confirm that this fits in with the Peer data given the size of the tumour and, on size grounds, it is possible that it is the same entity. But the Plaintiff extrapolates from the October measurement that the lump in May must have been cancer as it matches the Peer data. In fact, it only matches one of a huge range of doubling time rates, most of which doubling times would lead to a result that disproves the Plaintiff's case i.e. that the pea-sized lump was the wrong size.

11.30 To insist on only one possible doubling time ignores all the weaknesses set out by the expert for the defence in terms of relying on that data to estimate tumour size: including the use of mammograms, the fact that the data looked at a screening population, the women were all 41 or older if Professor Bundred was correct in Rossiter, the interval cancers were not included and no correction was made for them. This argument also ignores the proven facts of the case: an expert in imaging probed this area of this breast and did not see any malignant entity, let alone one that measured over one centimetre, but he did note and measure a cyst which matched the description given by the Plaintiff and the clinician in terms of where it was and how big it was.

11.31 On the issue of how big the lump was in May, there was mixed evidence. Professor Ellis said that there appeared to be *“discordance between the number of cysts, the position of those and the size and the clinical size that was palpated which was 15mm.”* He concluded: *“I would advise on the balance of probabilities that there would have been a residual mass and that that should have been biopsied.”*

11.32 This theory, that the palpable size was different to the imaging, was addressed by both Professor McNicholas and by Professor Bundred, both of whom gave evidence that 15mm palpated clinically was comparable to 12mm on ultrasound. In other words, that the pea-sized lump felt by the Plaintiff was comparable to the 12mm cyst described by the radiologist. Professor Bundred’s conclusion was contradicted by his own later evidence that the 15mm lump felt in May was unlikely to be the 12mm entity observed as it was a different size. Due to her vast experience and the temperate evidence she gave, I prefer the evidence of Professor McNicholas. Not only was her evidence given without the impression of bias already described in Professor Bundred’s evidence, it is also in line with common sense. It seems likely that there will be discrepancies between what a clinician can feel outside the breast and what a radiologist will measure on an ultrasound screen, in respect of the same entity. Professor McNicholas considered

that 3mm was not a big discrepancy. In her experience, a discrepancy of millimetres between clinical and radiological measurements was the norm, rather than being unusual.

11.33 The caveats expressed by Professor Crown as to the use of the Peer data, coupled with Dr. Allen's description of what should have been observed if this entity was indeed the pre-cursor to the October tumour and not a harmless cyst, help to identify the more probable narrative of events in this case, in my view.

12. The Plaintiff's experience

12.1 The Plaintiff felt that the lumps she first palpated in March of 2017 had not disappeared. She described them as having joined together or coalesced. The Plaintiff's evidence was that "it didn't move, just grew". The Plaintiff gave a description of events starting in March, including what occurred in May and August, her return in October, events after the diagnosis in October and her final appointment when she was told to come back in a year. In her evidence, she made it clear that from October onwards, her focus was on her treatment and was forward looking. She gave evidence that she had continued to self-examine in summer of 2017 and that she was certain that the lumps she felt in May had never disappeared but had coalesced.

12.2 Overall, her account was clear and did not appear to be exaggerated or fanciful in any way. She was thoughtful in how she answered questions. The Plaintiff was a witness who felt that she had been treated badly towards the end of her engagement with LUH and by Mr. Sugrue in particular. This appears to have arisen from the abrupt end to her treatment in 2018 and from a distressing discovery, after a traumatic year of treatment for cancer, that an appointment which she understood had been cancelled was marked in LUH records as an appointment which she did not attend.

12.3 Having understood that her cancer might return, the Plaintiff was told by the defence expert, Professor Crown, that she had an excellent prognosis given the time lapse between the treatment and the 5 years that has since elapsed. He noted that she appeared to be very relieved by this and that she had not been so advised. Professor Crown clearly respected the Plaintiff and was delighted that her treatment had been successful. He was critical of the level of communication by LUH with her, post-treatment. He repeated more than once that he was not setting himself up as a witness against the Plaintiff in any way, that he wished her well, did not doubt her sincerity and also emphasised the importance of listening to the patient in every case.

12.4 This impression of his evidence is set out here to explain the context for Professor Crown's evidence in relation to the question of what the Plaintiff said that she felt in July and August. He asked the Court: *"what is the difference between making a retrospective demonstration and saying: Can you feel this peppercorn or this lump? Or somebody who is in their shower puts their hand on their breast who is not a trained breast examiner noticing a very small lesion? Retrospection always make[s] things easier. I don't want to speculate about that. Again I would stoutly defend my contention that being really dogmatic about doubling times in this case is not appropriate."*

12.5 As the Plaintiff herself said in evidence, she spent over a year focusing on treatment and recovery. It was many months later when she began to question what had happened and look for explanations. While she, with hindsight, was satisfied that the lumps she felt in May and October were the same, the nature of simple cysts, the nature of what was seen in October, the ultrasound screen shots and a written report as to what was seen that day in May in a very specific and small area of the breast do not support that conclusion. There is no doubt that the Plaintiff's evidence was sincere, but the Court has to consider reliability also. Again, one must note that the Plaintiff was not taking notes or creating any record of what she could feel, nor was she measuring or noting its size or location. As Professor Crown put it, retrospection makes things easier.

12.6 In relation to this evidence, Professor McNicholas said that she was aware that the Plaintiff felt that what she had in October was the same lump she had felt in May. Asked if she doubted this, she replied, *“I don’t doubt that that’s what she feels but, you know, what was found on imaging is different.”*

12.7 Professor Arnold Hill was called as a clinical expert to give evidence in respect of the NCCP guidelines. At my invitation, this witness also addressed the Plaintiff’s evidence that the lump she felt in May never went away but became bigger. In that regard, he noted that a second cancer focus was identified in the imaging in October, it was in the region of eight o’clock, it was 7mm, and it was separate from the 34mm lump in the same quadrant of the breast. His belief was that the 34mm lump was different to what she was feeling, that it was not a tumour but continued to be cysts.

12.8 At the eight o’clock position in May there were multiple cysts, as is clear from the imaging, and these created nodularity for her, in the witness’s view, which she would have continued to feel. The witness took the view that there was a separate 34mm cancer starting at six o’clock not at 8 and in a deeper position in the breast than the peripheral lump palpated in May. Clinically, this witness took the view that the locations were different, although close. Professor Hill’s view was that looking at the pathology was definitive, rather than looking at an MRI in which the position of the breast would distort attempts to locate an entity. This is interesting given the pathologist, Professor Ellis’s, view that he would defer to the clinician as to where the entities were located.

12.9 Professor Hill’s evidence was very helpful. His answers were clear, including this sympathetic and persuasive account of how the Plaintiff may have believed that the lump in her breast had not disappeared. Similarly, Professor McNicholas had no hesitation in offering the view that her experience did not accord with the imaging. Neither witness discounted the Plaintiff’s views or questioned her honesty, but Professor Hill explained ways in which such physical phenomena might arise.

12.10 The most persuasive conclusion, in the Court's view, is that there probably were distortions or lumps in the Plaintiff's breast that did not disappear over the 5-month period described but, without more details in terms of measurements and location over time, this general evidence does not establish that the entities the Plaintiff could feel in May or in March were the same as the tumour in October.

12.11 The radiologist's report in May, coupled with the clear evidence as to what the tumour would look like had it been there at that point, weigh against this conclusion and persuade me that the Plaintiff, despite a genuinely held view that the lumps were the same, cannot provide evidence sufficient to counter the defence case on this point. It is no reflection on this Plaintiff or on any cancer patient to comment that while one must always listen carefully to the patient's account, the medical imaging, expertly explained, and notes of size and location usually provide more reliable evidence of size, appearance and location, rather than the relying on a patient's general description, particularly when the entity being described was not noted or measured contemporaneously by the patient. This is not a case in which there is no evidence as to what was seen in May: there is a contemporaneous report by a radiologist confirming a 12mm simple cyst in the same small area of the breast as the pea-sized lump and this Court has reliable evidence that this accords with a 15mm lump on palpation and that a simple cyst would look nothing like the tumour that was found in the Plaintiff's breast in October.

13. Locating entities in breast tissue and focal points

13.1 Asked if the location of the entity in May could be equated with the tumour found in October, Professor Bundred offered this evidence: *"when a woman gets a breast cancer, and... we know from the radiology that it was 36 millimetres the main one and 11 millimetres next to it ... 47 millimetres in a quadrant of the breast which is an A cup, the whole thing is going to be misshapen, it is going to change. The numbers are going to be different*

because the breast cancer will illicit an inflammatory response around it, HER2-positive cancers always illicit an immune response to some degree, whether it is an immune inert or an immune, but there is a lot of an immune response. And so therefore, the whole breast is going to be distorted. I mean, it is a huge lump in, whether we call it an A or B cup, it still a huge lump in a small breast and it is going distort them. So the mannequin is not really an accurate estimation because you cannot account for any of the distortion associated with the tumour."

13.2 This evidence was given to refute the defence position that the two entities were at different locations. It also, of necessity, suggests that the only fact of which the Court can be confident is that the pea-sized lump and the tumour were in the same quadrant of the breast. Given the distorting effect described by the Professor, it may not be possible to chart the two entities on a mannequin, as was done to demonstrate their respective positions, nor am I persuaded by his evidence, however, that the two must have been in the same location or that there is no purpose in identifying a probable location or focus for the two entities being considered.

13.3 As noted, the lump palpated in May was marked at 6 o'clock on the breast and measured as being 10cm from the nipple on the very periphery of the right breast. Dr Allen pointed out that this entity was very near the surface and with very little breast tissue around it so, referring to the radiological imaging *"the accuracy should be as high as it could possibly be."* As to movement of the breast and potential difference in location of a tumour in terms of palpation, he deferred to clinicians as being the relevant experts. Shown two ultrasound images of the entities in May and in October, his evidence was: *"As to whether they are the same thing, I think it is difficult to say because I wasn't there in May doing that ultrasound."*

13.4 On the topic of location, this witness made the suggestion that the lump measured in May could not have been 10cm from the nipple as this would have been on the chest wall, the breast not being large enough to accommodate that measurement. This led to some robust challenges. Insofar as it is necessary to resolve

this issue, the Court is satisfied that it is unlikely to be correct. Firstly, the measurements taken were not questioned or corrected by the Plaintiff or by the radiologist on the day, nor has the Plaintiff ever suggested that the clinician marked the wrong part of her body and, crucially, the process whereby this was queried by reference to the Plaintiff's breast in 2022 ignored the fact that she had undergone reconstructive surgery in the meantime. There is no reliable basis for the Court to find that the initial measurement of 10cm went outside the area of breast tissue as suggested and indeed the theory was not raised again in submissions. This theory reduced the reliability of the witness's evidence in respect of location of any entity but I remained confident that his views on the radiological aspects of his evidence, as to the appearance of cysts and tumours which was his area of expertise, were reliable.

13.5 When Professor Ellis was questioned on the issue of where the measured lumps were in May and in October, he said that he would defer to a clinician. In respect of location, Professor McNicholas was of the view that the cancer, in October, had started in or around the 6 o'clock position on the clock face, given what she was seeing in radiology in all the imaging, whether MRI or ultrasound. She allowed that the tumour in October was large and spread across and over 6 and 8 o'clock. She explained that the largest entity was probably the origin of the cancer and the focal point, in her view, was 6 o'clock. While Dr. Allen disagreed and said it stretched from 6 to beyond 8 o'clock, having viewed the images in question, the evidence on the whole appeared to this Court to establish a likely focus nearer 6 o'clock than 8.

13.6 Most witnesses agreed that one could not be very precise in terms of location when one had no image of the entity in May and given that the different modalities of imaging involved the woman being in different positions which would produce different results as the tissue in her breast moved. As noted, this whole area of cross-examination was thrown into question somewhat by Professor Bundred, who took the view that the distortion of the breast when the tumour had grown to 34mm, was such that any attempt to pinpoint an earlier location was futile.

13.7 Given that all the other experts engaged with this exercise, I have reached a tentative view on the likely location of the focus of the lesion in October, namely that it was at or near 6 o'clock. Most witnesses took the view that it was very difficult to be precise about the exact location of an entity in living tissue. Despite some more firmly stated views, the evidence on this issue was very mixed and there was insufficient evidence to positively prove that the tumour found in October originated in the same location as the pea-sized lump in May.

13.8 It was argued that it could not be a coincidence that there was a lump in the breast and, five months later, a tumour in the same quadrant of the same breast. There was no evidence to suggest that a woman could not have a cyst, that creates a lump, in one quadrant of the breast while a separate cancer was growing in the same quadrant. Given the evidence that cysts are a common feature in the female breast, this does not seem to be a coincidence that should cause concern nor does it require a link between the two.

14. The Implied Hearsay letter

14.1 In considering the plausibility of the 'interval cancer' theory, the Plaintiff drew attention to the letter of Dr. Michael McCarthy, Consultant Oncologist, of the 22nd October, 2017. In this correspondence, he states in relation to the original assessment of the Plaintiff's breast lumps that "*at the time these were thought to be cysts*". Professor Ellis, in his evidence, said it was reasonable to infer that Dr. McCarthy thought that these lumps were cancerous and that they should have been biopsied. It was submitted that the Court should take Dr. McCarthy's views into account.

14.2 In this litigation about the evidence which supports or refutes the presence of a detectable cancer at a particular time, the Court cannot place any weight on a sentence in a letter, written by a doctor not called as a witness at a time when he could not have known more details about the case than are apparent from the medical notes.

Even a detailed reading of those notes would suggest that his synopsis was incorrect insofar as the comment appears to infer that the cysts were in fact tumours. His comment to this effect has not been tested here, the Court does not know the basis for it, the parties have had experts set out and defend, in detail, two different positions on the question and the Court has decided the case on the basis of their evidence, not on a comment in a letter which appears to reach a conclusion as to what was present in May without explaining the reasoning involved.

14.3 Professor Ellis did agree with counsel's suggestion that Dr. McCarthy's comment might have indicated a view that a biopsy should have been carried out in May, but he was not certain. The comment cannot be read this widely, it seems to me, and the witness was right to be cautious about adopting that view. Whatever about an assumption that the lump must have been cancer as it was in the same area of the breast, it is a step further again to say that the comment imports a criticism of the treating clinician to the effect that he should have acted in a particular way. It is a step this Court is not prepared to take and again it must be emphasised that the writer of the letter was not called to explain or expand upon this comment. That being the case, it is an example of implied hearsay evidence and it is inadmissible to prove the truth of the implication in the statement, namely, that the lumps were not cysts.

15. Conclusions

15.1 The Plaintiff attended LUH in May of 2017 with multiple cysts, having noted two lumps in her breast. The radiologist probed the pea-sized lump marked by the surgeon and, in his report, stated that he had concentrated on the marked area and found only cysts, including one large enough to be responsible for that lump.

15.2 Professor Bundred has relied on the Peer data without sufficient latitude to incorporate the possible range of doubling times indicated in later papers and without factoring in the bias in the Peer data. Further, he has been too inclined to select a

doubling time rate to accord with the size of the lump. His evidence is further weakened by evidence he gave in an earlier case. Because of these factors, and others in respect of the manner of his evidence generally, outlined above, the reliability of his evidence is considerably reduced. It seems to the Court, having read the literature provided and having considered the evidence put forward to justify that theory, that the Plaintiff has not established that there was a 15mm cancer in May or that the pea-sized lump palpated was one and the same as the cancer detected in October. It is more likely that the radiologist's report is accurate as to what was seen and the 12mm cyst caused the lump. If this is so, had it been aspirated, it would probably have disappeared. None of which would have prevented the continuing growth of a separate cancer in the same quadrant of the breast.

15.3 As a matter of fact, I am satisfied that the radiologist did probe the marked area. Bearing in mind the evidence of Dr. Allen, I am satisfied that Dr Mac A'Bhaird did not see an obvious tumour in May, the same as the tumour in October, but smaller. Noting how Dr. Allen and Professor McNicholas described simple cysts and noting all the relevant facts of this case, I am satisfied that a radiologist of this experience probably did not miss a 15mm tumour completely, nor did he see an obvious tumour and mistake it for a simple cyst. He probably saw what was described in his report: a 12mm cyst.

15.4 The Peer data may be accurate insofar as it goes, but it may also be misleading. All that is required to identify the limitations of such data is to establish that there could be cancers that are either faster or slower growing than those in that data. Faster mean rates of growth and individual instances of faster growth rates can be seen from the data in subsequent papers cited and handed in to the Court.

15.5 No calculation was done other than one based on a carefully chosen 45-day doubling time. This was the only case presented to the Court and it probably has been chosen to correlate the estimated growth with the actual size of a lump palpated in

May. It may not have been done deliberately to bolster the Plaintiff's case, but this is its effect. Choosing this exact doubling time is the Goldilocks phenomenon referred to by Professor Crown: the lump is exactly the right size but only if you use the 45-day doubling time. Any other rate and the size of the lump changes and the theory that the pea-sized lump in May was the tumour collapses as a lump bigger or a smaller than a pea is not consistent with the facts the Plaintiff must prove.

15.6 The Plaintiff's submissions were to the effect that the growth rate of the cancer was "*off the charts*" if the defence theory is correct. But the charts are limited to cancers growing at a particular speed in 289 women, all over a certain age, whose records were assessed in the early 90s. If this tumour was growing faster, which appears likely, then it was off the charts, as are many aggressive cancers that grow too fast for similar studies, using two measurements taken at different times, to identify them. There was no evidence from the Plaintiff that a doubling time faster than that recorded in Peer's data would still have meant the tumour was detectable and the expert's evidence was all directed to defending the stated position that the most likely doubling time was 45 days and that the pea-sized lump was cancer. It is not possible to be this certain about the potential doubling time of a tumour based on average figures taken from the Peer paper.

15.7 The Plaintiff's allegations of negligence in respect of aspiration and concordance only arise if the tumour was detectable in the first place. Looking at Dr. Allen's evidence, and at his report, it is clear that the basis for his view of the case was that the doubling time theory of Professor Bundred was accurate and reliable. The only two views of the case that he could put forward (that the radiologist did not, in fact, check the marked area or that he did but still somehow missed this obvious cancer) were not the only possible views. The one he did not consider, as it was not referred to in Professor Bundred's report, was a cancer growing at a rate faster than the range recorded in the Peer data, a cancer that was present, but not detectable in May. The radiologists all agree that the tumour in October was not different in

appearance to the tumour in its early months of development. The evidence of what was seen on ultrasound in May, including images of simple cysts and a measured cyst of 12mm at the site of the pea-sized lump, establishes that the lump was probably a simple cyst. The Plaintiff has not proven that the pea-sized lump was a tumour, although all agree that the tumour probably was present in May. If so, it was probably undetectable at that point.

15.8 The Court will not go on to consider the arguments in relation to aspiration and concordance in the circumstances. If the pea-sized lump was probably a cyst, then even if there was negligence (and I make no such finding as it is unnecessary) there was no mis-diagnosis and negligence could not cause the alleged damage to the Plaintiff, which was probably caused by an interval cancer as described above.

15.9 The Court will hear the parties in relation to costs.