THE COURT OF APPEAL

UNAPPROVED
NO REDACTION NEEDED

Neutral Citation Number: [2021] IECA 141
Record Number: 2021/29
High Court Record Number: 2018/6109P

Noonan J.

Faherty J.

Collins J.

BETWEEN/

VIVIENNE WALLACE

PLAINTIFF/RESPONDENT

-AND-

HEALTH SERVICE EXECUTIVE AND

SONIC HEALTHCARE (IRELAND) LIMITED AND

AND MEDLAB PATHOLOGY LIMITED AND

CLINICAL PATHOLOGY LABOROTORIES INCORPORATED

FOURTH NAMED DEFENDANT/APPELLANT

Record Number: 2021/24
High Court Record Number: 2019/4939P

BETWEEN/

CAOIMHE O'NEILL FORDE

PLAINTIFF/RESPONDENT

- AND –

HEALTH SERVICE EXECUTIVE AND

SONIC HEALTHCARE (IRELAND) LIMITED AND

MEDLAB PATHOLOGY LIMITED AND

CLINICAL PATHOLOGY LABORATORIES INCORPORATED

FOURTH NAMED DEFENDANT/APPELLANT

Record Number: 2021/25
High Court Record Number: 2018/10201P

BETWEEN/

JOAN O'FLYNN

PLAINTIFF/RESPONDENT

- AND –

HEALTH SERVICE EXECUTIVE AND

SONIC HEALTHCARE (IRELAND) LIMITED AND

MEDLAB PATHOLOGY LIMITED AND

CLINICAL PATHOLOGY LABORATORIES INCORPORATED

FOURTH NAMED DEFENDANT/APPELLANT

Record Number: 2021/26
High Court Record Number: 2018/6277P

BETWEEN/

LORNA DOHERTY

PLAINTIFF/RESPONDENT

- AND –

HEALTH SERVICE EXECUTIVE AND

SONIC HEALTHCARE (IRELAND) LIMITED AND

MEDLAB PATHOLOGY LIMITED AND

CLINICAL PATHOLOGY LABORATORIES INCORPORATED

FOURTH NAMED DEFENDANT/APPELLANT

Record Number: 2021/27
High Court Record Number: 2018/9078P

BETWEEN/

GRAINNE McNALLY AND MICHAEL WARREN

PLAINTIFF/RESPONDENTS

- AND –

HEALTH SERVICE EXECUTIVE,

SONIC HEALTHCARE (IRELAND) LIMITED,

MEDLAB PATHOLOGY LIMITED AND

CLINICAL PATHOLOGY LABORATORIES INCORPORATED

FOURTH NAMED DEFENDANT/APPELLANT

Record Number: 2021/28
High Court Record Number: 2018/6513P

BETWEEN/

JUSTINA HURLEY

PLAINTIFF/RESPONDENT

- AND –

HEALTH SERVICE EXECUTIVE AND

QUEST DIAGNOSTICS INCORPORATED AND

MEDLAB PATHOLOGY LIMITED AND

SONIC HEALTHCARE (IRELAND) LIMITED AND

CLINICAL PATHOLOGY LABORATORIES INCORPORATED

FIFTH NAMED DEFENDANT/APPELLANT

JUDGMENT of Mr. Justice Noonan delivered on the 11th day of May, 2021

1. The plaintiff in the first named proceedings above, Ms. Wallace, is one of a number of plaintiffs who have brought proceedings arising out of the operation of the State's CervicalCheck Screening Programme. Ms. Wallace underwent a smear test on the 14th September, 2010 and again on the 17th July, 2013. Both tests were reported as normal. In October, 2014, Ms. Wallace was diagnosed as having cervical cancer. In these proceedings, she alleges that the defendants were negligent, *inter alia*, in failing to properly consider and interpret her cervical samples and reporting them as normal when they were in fact abnormal.

2. When a cervical sample is taken for screening purposes, it is ultimately placed on a pathology slide which is examined by expert technicians known as cytoscreeners or cytologists. The National Screening Programme was operated by the first defendant via cytoscreening services provided at laboratories operated by the second, third and fourth defendants. The cervical sample, when received by the laboratory, is prepared for analysis by being placed in a pathology slide which covers the biological material with a glass covering. The slide is examined under a microscope at different resolutions and any abnormalities are noted by the screener marking the slide by highlighting the areas of

abnormality with different types of markings. In 2010, the National Screening Programme required screening by two cytoscreeners, in turn. Further to their respective analyses, the slide may or may not be marked by one or both of them. In Ms. Wallace's case, for example, the screening carried out is evidenced by the presence on the slide of one red and one blue marking referable to the original screening.

3. In cases where there was a subsequent diagnosis of cervical cancer, the slides of the women concerned were reviewed in a Cancer Audit Review (CAR). During the course of this review, further markings were applied to the slides highlighting other areas of concern identified by the reviewers in the CAR. In the Wallace case, for example, the CAR is evidenced by the presence of eleven black circles and one half circle on the slide. Consequently, many of the slides show two sets of markings, those applied by the original cytoscreeners and those applied in the course of the CAR. In many cases, there is a third set of markings applied in the course of a later review conducted by the Royal College of Obstetricians and Gynaecologists.

4. A significant number of women, including the plaintiffs in these six appeals, have instituted proceedings in the High Court arising out of their participation in the CervicalCheck Programme in circumstances similar to Ms. Wallace. This litigation has been managed by the judge with responsibility for the management of the High Court Personal Injuries List, Cross J., who was also the trial judge in the leading case *Morrissey v HSE* [2019] IEHC 268, [2020] IESC 6.

5. During the course of managing this litigation, an issue arose concerning the manner in which patient slides were to be dealt with.

6. The slides reside in the laboratories where they were originally analysed for the screening programme. Each plaintiff's original slides require to be reviewed and analysed

by experts advising that plaintiff, giving rise to the necessity for a procedure to be in place which provides for the transfer to and return from those experts of the relevant slides. A debate ensued between the parties as to how this objective could best be achieved and Cross J. heard argument and submissions for the purpose of devising a protocol that would apply to all cases. The final product of that process of engagement is designated "Final Protocol 25 January 2019" ("the Protocol"). This document was approved by Cross J. and directed to be lodged in court.

7. The Protocol provides for the manner in which slides are to be made available to plaintiffs and after examination returned to the relevant laboratory. The Protocol also provides for digital imaging of the slides before release. The focus of the applications the subject of these appeals is Clause 4 of the Protocol which provides as follows: -

> "4. Any existing markings, save for the cancer audit markings, are not to be removed or any new markings applied to the slide(s) without the prior approval of the court. Unless otherwise agreed between the parties in writing, the removal of the cancer audit markings can only occur following the review of the slide by the expert engaged by the requesting patient or legal representative of the patient or deceased patient and on the basis that, any removal of cancer audit markings will only be undertaken by the relevant laboratory contracted to the HSE/NSS. It is acknowledged by the HSE/NSS that if a patient or their representative requests the removal of such markings, the HSE/NSS will procure their removal by the contracted lab as soon as practicable. Prior to the removal of any such markings, the laboratory in question will be required to image the slide(s) in accordance with paragraph 8 below."

8. As appears from the foregoing, the cancer audit markings on any given slide may be removed without a court order subject to the terms of clause 4. However, any other

markings, such as the markings made by the original cytoscreener(s) may not be removed save by order of the court. The Protocol does not address the position of any markings that may have been applied in the course of the review conducted by the Royal College of Obstetricians and Gynaecologists.

9. The applications the subject of these appeals are brought by the fourth defendant/appellant ("CPL") who sought leave from Cross J. to remove all markings from Ms. Wallace's slides for the purpose of carrying out what is referred to as a "blind review".

10. CPL's application is grounded upon the affidavit of its solicitor, Margaret Muldowney, sworn on 11th January, 2021. Ms. Muldowney's affidavit is made based on instructions received from her client, CPL. In particular, she avers the following at para. 8: -

> "8. While I acknowledge that the rationale and arguments for the removal of the markings on the slide in the instant case are more properly matters for submission, I say and have been advised by the fourth named defendant that the removal of the markings will facilitate the presentation of expert evidence based upon an examination of the slide as it would have been examined by the cytoscreener on or around 18 October, 2010, being the date of the screening during which it is alleged that the negligence and breach of duty occurred. In addition, I say and am advised that an examination of the slide absent of markings limits, to the extent possible, hindsight bias and/retrospection. Furthermore, as the integrity of the slide will not be compromised there can be no prejudice or disadvantage to the plaintiffs if liberty is granted to remove the markings."

11. This affidavit was responded to in a replying affidavit sworn by Alaina Hogan, Ms. Wallace's solicitor, sworn on 18th January, 2021. In this affidavit, Ms. Hogan questions the utility and value of blind reviews and suggests that (at para. 7): -

> "7. … As confirmed in [the Morrissey] case, blind reviews are not necessary for the determination of whether there has been a breach of duty in the examination or interpretation of a slide. As such, blind reviews are of little or no evidential value."

12. As the argument in these appeals demonstrated, that statement is, to say the least, controversial. Ms. Hogan goes on to articulate the reason for the plaintiff's opposition to CPL's application in the following terms (at para. 9): -

> "9. For the reasons stated in the correspondence the plaintiff is opposed to the removal of any markings from the slides. Whilst it is more properly a matter for submission, the primary reason for the plaintiff's opposition to the removal of the markings is as follows: The markings made on the slide by the original screeners are the only evidence recorded of what was observed on that slide by those original screeners. Their observations are uniquely captured by both the markings and cells at those locations. If the markings are removed this will amount to the irreversible and unwarranted destruction of that physical evidence solely for the purpose of a blind review that is itself of little or no evidential value."

13. At the hearing of this appeal, CPL argued strongly that there could be no actual prejudice to the plaintiff by the removal of the markings in circumstances where her expert, Professor McKenna, has already had ample opportunity to examine the relevant slide(s) and where, in addition, it is proposed that digital imaging of the relevant slides at appropriate magnifications be undertaken which will create a permanent record of all markings on the slides prior to their removal. Those measures will, it is said, eliminate any potential prejudice to the plaintiff. Counsel for the plaintiff in the course of argument fairly admitted that he could not identify, at this juncture at any rate, any specific prejudice that would be incurred

by the plaintiff by the removal of the markings provided that the steps proposed by CPL were taken.

14. The application came on for hearing before Cross J. on the 19th January, 2021. Counsel for CPL indicated to the court that, as averred by Ms. Muldowney, the reason for the application was to permit the litigated slides to be examined in the same form as the cytoscreeners examined them and to reproduce as closely as possible the original screening conditions. This would limit, to the extent possible, any hindsight bias. The court noted that the plaintiff's expert had already had the opportunity of examining the slides in their original unaltered condition.

15. It was also suggested by counsel for CPL that the plaintiff's expert could take any images of the slides that were in his opinion necessary to create an appropriate permanent record of what markings appeared on the slides prior to their removal. Counsel for the plaintiff, in opposing the application, suggested that CPL had come late into the case for various reasons and was now seeking to do something that their co-defendant sister companies had agreed should not be done, in the course of argument leading to the development of the Protocol.

16. However, the primary submission made by counsel for the plaintiffs is that it is implicit in the terms of the Protocol that an applicant seeking to remove markings has to show special or exceptional circumstances in effect to justify a departure from what would otherwise be the status quo. Counsel also contended that there was complexity and controversy concerning the issue of hindsight bias, as more particularly explored in *Morrissey*. Counsel further submitted that there was no evidence before the court that could justify the making of the order as sought by CPL. In particular, the court had no evidence as to how this issue is approached in any other jurisdiction or, indeed, if it is undertaken at

all in any other jurisdiction. Counsel submitted that there was no evidence on affidavit from an expert to state what the actual evidential benefits of a blind review are. Counsel argued that it was inappropriate to grant the order as sought based on the affidavit of a solicitor.

17. Having considered the arguments, Cross J. delivered an *ex tempore* judgment, during the course of which he said (at p. 32-33 of the Transcript of the 19th January, 2021): -

> "And Mr. Treacy also says that the applications are in effect to turn on its head the provisions of the Protocol and in particular paragraph 4 which posits as the normal position that the slide – that the markings are not to be removed and it is only by application to the court that they should.
>
> And Mr. Treacy submits that this means that it is only in exceptional circumstances that the – what is envisaged in protocol should be departed from. And I agree with him that that is the norm of the Protocol and that it is therefore something that is to be departed from only in exceptional circumstances."

18. On the issue that had arisen during the hearing as to whether the application should be adjourned for an affidavit to be filed by the defendant's experts deposing to what happens in other countries, Cross J. indicated that he was not disposed to adjourn the application and continued (at p. 33-34 of the Transcript): -

> "… I quite frankly do not see that the defendant has established special circumstances that would be required to make me depart from what the Protocol is (*sic*) hammered out and essentially agreed by all the then parties to the matter. And I think it is a fair protocol.

> I don't see that it is necessary to remove the markings to conduct a blind review that can be done and if that is considered to be desirable. And accordingly I will refuse this application …"

19. This appeal is one of a cohort of six appeals named in the title above. It is treated as the lead appeal which governs the others. The primary ground of appeal is that the trial judge was in error in holding that there was a requirement for CPL to establish exceptional or special circumstances in order to obtain the leave of the court pursuant to para. 4 of the Protocol to remove the markings on the slide.

20. There was considerable debate in these appeals as to the nature of the Protocol and how it should be interpreted. In their written submissions, CPL suggested that while it might be argued that the Protocol should be regarded as a form of contract between the parties concerned, whether that was so or not, it was appropriate to apply relevant rules of construction as developed by the courts to the interpretation of contracts and, in particular, the "text in context" approach.

21. I am not persuaded that it is appropriate to regard the Protocol as some form of contractual document. That is not least because of the fact that it is at any time, as counsel for CPL conceded, amenable to change at the direction, or instigation, of the High Court. Neither is it a document to be construed and given effect to as if it were a statute. It does not have that status. The closest analogue is probably that of a practice direction or, perhaps more accurately, a case management direction. As such, it is a measure introduced by the court to better manage and regulate complex multi-party litigation on a large scale.

22. As a general proposition, an appeal court will be slow to interfere with a case management order made by a court of first instance. As Clarke C.J. noted in *Dowling & Ors v Minister for Finance & Irish Life & Permanent Plc* [2012] IESC 32 (at para. 3.1 on): -

> "3.1…Case management only works if there is broad adherence to the directions given by the Court. The trial court must retain a very large measure of discretion over the directions which are appropriate and the measures to be adopted in the event of a failure to comply. There would be no reality to the achievement of the undoubted advantages which flow from case management if this Court were, on anything remotely resembling a regular basis, to entertain appeals from parties who were dissatisfied with either the precise directions given or orders made by the Court arising out of failure to comply….
>
> 3.5 Against that background it seems to me that this Court should only intervene if there is demonstrated a degree of irremediable prejudice created by the relevant case management directions such as could not reasonably be expected to be remedied by the trial judge (or at least where the chances of that happening were small) and where therefore, unusually, the safer course of action would be for this Court to intervene immediately to alter the case management directions..."

23. Case management measures such as the Protocol do not in any sense displace the court's inherent jurisdiction to make whatever order in a particular case that justice requires, guided, as appropriate here, by the provisions of the Protocol. The order sought by CPL might on one view be said to be not merely a case management order in the sense of being amenable to being revisited but rather a matter going to the very heart of its defence. That is indeed how it is characterised by counsel for CPL. Counsel emphasises that the refusal of the order sought by it has far-reaching effects for CPL's defence of the proceedings in that CPL will, for once and for all, be precluded at trial from making the case it says it wants to make, based on expert review of the slides in the condition they were when first presented for screening. Counsel for the plaintiffs argued, on the other hand, that the removal of the

markings applied by the original cytoscreeners constituted the eradication of critically important original evidence. Counsel argues that the issue is not what is on the slides but what the cytoscreeners did or did not see on the slides. This, it is said, is the basis for the allegations of negligence made by the plaintiffs.

24. As Clarke C.J. noted in *Dowling* (at para. 3.2), in *P.J. Carroll v Minister for Health and Children* [2005] 1 I.R. 294, an appeal from a case management order was allowed "precisely because it involved a very important aspect of the process in the case in question which concerned the entitlement of the defendant Minister to lead expert evidence." The appeal here appears to me to raise a similar issue and, for that reason, this Court must carefully scrutinise the decision of the High Court, without any exaggerated deference or self-restraint. Essentially, this Court must consider whether the order made by the High Court was correct.

25. I am not persuaded that there is any warrant for implying into the Protocol a requirement for a party to demonstrate special or exceptional circumstances before an order pursuant to Clause 4 can be made, as the trial judge held. However, neither can I accept CPL's proposition that an order is to be made for the asking, subject only to a right to object by demonstrating prejudice. As I have said, the default position agreed between the parties is that markings are not to be removed unless and until the court allows it.

26. It seems to me inherent in this that there is at least some threshold to be crossed by an applicant for an order under Clause 4 which requires that party to adduce appropriate and admissible evidence as to why the default position should not obtain. Obviously central to that analysis is the issue of prejudice. Although counsel for Ms. Wallace repeatedly emphasised that such application involved the destruction of original evidence, while that

may be so, it does not in and of itself give rise to a conclusion that this is a reason, without more, for refusing an application properly made, grounded on appropriate evidence.

27. The plaintiff maintains that blind reviews have no evidential value and that, in any event, there are forms of blind review which can be undertaken without the need for the original screeners' markings to be removed. It is apparent from the judgments given in the High Court and in the Supreme Court in *Morrissey* that there was significant controversy in that case about the value of blind reviews, how such reviews ought to be conducted, the impact of hindsight bias and whether and how it can avoided and related matters. The judgments in *Morrissey* do not purport to resolve those controversies: see the comments of Clarke CJ at [2020] IESC 6, para 10.10 These issues cannot properly be resolved on a case management application of this nature. They can only be resolved at trial, on the basis of the expert evidence adduced.

28. CPL argues that it is entitled to present its case in whatever way it considers will secure for it a litigious advantage. If there is appropriate admissible evidence which, on its face, demonstrates that, absent the removal of the markings, CPL may suffer a litigious disadvantage by being denied the opportunity to carry out a blind review as it wishes to do, then in my judgment that is a proper basis on which to make such an application.

29. It seems to me that it would be necessary for CPL to adduce appropriate expert evidence in this regard to enable to High Court to properly adjudicate on this issue. That evidence would have to specify with particularity the precise steps proposed and how in the opinion of the relevant expert, the proper defence of CPL's position would be prejudiced to its litigious disadvantage by the absence of such steps. The evidence would have to satisfy the High Court that there is a real risk that CPL's defence may be prejudiced if it is not permitted to undertake this exercise. It does not have to go further than that, however, and

I again emphasise that the respective putative merits and disadvantages of different kinds of blind review are not something that the court can determine in an interlocutory application of this nature. That is a matter for the trial.

30. On any such application, the court will have to consider whether there are countervailing circumstances that militate against the making of such order, and, in particular, whether there is any demonstrable prejudice to the plaintiff, either actual or apprehended. The court will in such an application, as in all litigation, be concerned with striking a balance between the respective rights of the parties so as to do justice in the particular case. If the evidence establishes (to the extent indicated above) a real risk that the refusal of the order sought would deprive CPL of a legitimate litigious advantage in these proceedings, then in the absence of any compelling countervailing consideration, the balance of justice would clearly favour making the order sought.

31. I am of the view that the trial judge was in error in requiring CPL to demonstrate special or exceptional circumstances. The trial judge was also in error in suggesting that it was not necessary to remove the markings to conduct a blind review. There may be forms of blind review that can be undertaken without removing the markings but the removal of the markings is an absolute pre-requisite for the form of blind review that CPL wishes to have carried out. In this context, it is notable that in his evidence in *Morrissey* Professor McKenna seems to have criticised the blind review undertaken in that case precisely because the slide had markings on it *"and therefore was not a true reproduction of what was before original screener*". CPL wishes to avoid any such criticism here.

32. Even though the judge was wrong to dismiss the application on the basis that he did, I agree with the argument advanced for the plaintiff that there was no sufficient evidence before the trial judge that should have entitled CPL to the order sought. In reality, the only

evidence put before the High Court was an affidavit of a solicitor advising the court that her clients had instructed her that they believed a blind review was a good idea.

33. In an interlocutory application of this nature, the appropriateness in general of a solicitor swearing an affidavit containing obvious hearsay may fall to be considered. It is sometimes assumed that parties have a right to adduce hearsay evidence in interlocutory application by virtue of the provisions of O. 40 r. 4 of the RSC. That this is not so is made clear by the judgments in *F. & C. Reit Property Asset Management Plc v Friends First Managed Pensions Funds Ltd* [2017] IEHC 383 and *Joint Stock Company Togliattiazot v Eurotoaz Ltd* [2019] IEHC 342. The admission of such evidence is the exception rather than the rule and the true position is that the court may agree to admit such evidence where there is a cogent explanation for the non-availability of direct evidence, for example, where it is not practicable to obtain such evidence for reasons of urgency. However, the trial judge did not take any point on this.

34. But ignoring that issue for present purposes, I do not think by any stretch the solicitor's affidavit here could be regarded as a satisfactory basis to ground such an application for the reasons I have already explained.

35. Having regard to the foregoing and in particular to the systemic importance of such applications to this category of litigation, I am of the view that the appropriate course is for this court to set aside the order of the High Court and remit these applications to that court to be reconsidered in the light of such further evidence as the parties may wish to adduce. It will be a matter for the High Court to give such further directions concerning the exchange of further affidavits as to that court seems appropriate.

36. With regard to costs, although it might be said on one view that CPL has to some extent been successful in this appeal in that it has resulted in the setting aside of the order of the

High Court, nonetheless it seems to me that the High Court would have been justified in rejecting the application on the grounds I have identified, namely that there was no proper evidence before the court which warranted the making of the order sought. That shortcoming, in my view, is entirely the responsibility of CPL and had such evidence been available at first instance, the necessity for this appeal might have been entirely avoided. My provisional view, therefore, is that Ms. Wallace should be entitled to the costs of this appeal and of the application in the High Court. If CPL wishes to contend for a different order, it will have liberty to apply to the Court of Appeal Office within 14 days for a brief supplemental hearing on the issue of costs. If such hearing is requested and results in the order proposed, CPL may additionally be required to pay the costs of such hearing.

37. As this judgment is delivered electronically, Faherty and Collins JJ have indicated their agreement with it.