

THE HIGH COURT

[2021] IEHC 681

[Record No. 2018/6109 P.]

BETWEEN

VIVIENNE WALLACE

PLAINTIFF

AND

**HEALTH SERVICE EXECUTIVE, MEDLAB PATHOLOGY LIMITED, SONIC HEALTHCARE
(IRELAND) LIMITED AND CLINICAL PATHOLOGY LABORATORIES INCORPORATED**

DEFENDANTS

Judgment of Ms. Justice Reynolds delivered on the 26 October, 2021

Introduction

1. This is an application brought by the fourth named defendant, Clinical Pathology Laboratories Incorporated ("CPL") seeking, *inter alia*, the following relief:

"An order granting liberty to remove all markings from the slide in respect of the smear test taken on the 14 September 2010 numbered ZA322603 in accordance with paragraph 4 of the Final Protocol of the 25 January 2019."

2. The application was originally moved before Cross J. on the 19th January, 2021. That application was refused and thereafter appealed by CPL.
3. On the 11th May, 2021, Noonan J., delivering judgment on behalf of the Court of Appeal, set aside the order of Cross J. and remitted the application back to the High Court to be reconsidered in light of further evidence to be adduced.
4. On the 15th July, 2021, Coffey J. directed a further exchange of affidavits and legal submissions.

Background

5. The plaintiff, Ms. Wallace, is one of a number of plaintiffs who have brought proceedings arising out of the CervicalCheck Screening Programme.
6. Ms. Wallace underwent two cervical smear tests, one on the 14th September, 2010 and a further one on the 17th July, 2013. Both tests were reported as normal.
7. In October, 2014, Ms. Wallace was diagnosed as having cervical cancer.
8. In the within proceedings, it is alleged, *inter alia*, that the fourth named defendant misread the slide in respect of the smear test taken on the 14 September 2010 and as a result the plaintiff's cancer was allowed to develop and/or spread until her diagnosis in 2014.

The screening process

9. The judgment of the Court of Appeal, delivered on the 11th May, 2021, very helpfully summarises the manner in which cervical samples are taken for screening purposes and analysed thereafter: -

- "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."
10. Ms. Wallace is one of a significant number of women who have instituted legal proceedings arising out of her participation in the CervicalCheck Screening Programme.

Application to remove markings

11. The within application arose in circumstances where CPL, by letter dated the 2nd December, 2020, sought the plaintiff's consent to an order for the removal of all markings from the slide of the smear test taken on the 14th September, 2010 in accordance with para. 4 of the Final Protocol of the 25th January, 2019.
12. That Protocol was compiled to govern access to and the examination of patient slides in the course of ongoing litigation. It provides for the manner in which slides are to be made available to plaintiffs and after examination returned to the relevant laboratory. It further provides for digital imaging of the slides before release.
13. Paragraph 4 of the Protocol states: -
- "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."

14. It is evident that the cancer audit markings on any given slide may be removed without a court order subject to the foregoing terms of para. 4 of the Protocol. However, any other existing markings such as the markings made by the original cytoscreener(s) may not be removed save by order of the court.
15. In relation to Ms. Wallace, it is common case that the expert retained on her behalf had the relevant slide for a period of thirteen months for the purpose of reviewing and imaging same and further, that digital imaging of the slide was procured before its release.
16. In the context of the within application, CPL is essentially seeking to carry out what is referred to as a "blind review" of the slide in respect of the smear test taken on the 14 September 2010. The slide was marked during the original screening process by CPL and during a subsequent cancer audit review conducted by the third named defendants, servants and/or agents.
17. CPL contend that in order to recreate the conditions under which the slide would have been read by a cytoscreener, it is necessary to have the markings removed from the slide so that an expert is placed in the same position as the original cytoscreener.
18. On the 19th January 2021, Cross J., in refusing CPL's application to remove all markings from the slide held that CPL had not met the requirement under para. 4 of the Protocol to demonstrate special or exceptional circumstances to justify such removal.
19. The Court of Appeal (at para. 25) of its decision disagreed with the necessity to demonstrate special or exceptional circumstances and stated as follows: -

"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".

20. Noonan J. went on to emphasise 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.”.

21. Further, the Court of Appeal determined that the granting or refusal of the order directing the removal of the markings could not turn on what type of blind review was going to be performed by CPL and noted at para. 28 as follows:

“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.”

The test to be applied

22. Noonan J. at paras. 29 and 30 of the judgment proceeded to set out the test to be applied in considering the within 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”.

23. As appears from the foregoing, there are two specific limbs to the test in determining whether the threshold has been reached for such an application to be successful.
24. Firstly, CPL must adduce evidence that absent the order for removal of the markings for the purposes of a blind review, it will suffer a “litigious disadvantage” in the manner in which it can defend the proceedings giving rise to a real risk that its defence may be prejudiced.

25. Secondly, the court must consider if there any “countervailing circumstances that militate against the making of the order”, having particular regard to “any demonstrable prejudice to the plaintiff”, whether actual or apprehended.
26. Thereafter, the court is required to engage in striking a balance so as to do justice to the interests of the parties.

The evidence

27. CPL relies on the evidence of Ms. Alison Cropper to establish that the presence of the marks on the slide gives rise to a real risk of hindsight bias and that a refusal of the order to remove them will deprive CPL of an opportunity of presenting evidence which would not be tainted by such bias.
28. Ms. Cropper’s affidavit, sworn on the 14th July, 2021, demonstrates as follows:
 - (a) Ms. Cropper is a cytologist.
 - (b) Ms. Cropper points to the very significant risk of hindsight bias when a slide is being reviewed by a cytologist who has knowledge that the patient has gone on to develop invasive cervical cancer. That is because the person reviewing the slide expected – in light of that knowledge – to find abnormalities in the slide. Ms. Cropper noted at paragraph 5 of her affidavit that:

“This creates hindsight bias and does not replicate the original screening exercise”.

At para.s 10 and 11 Ms. Cropper avers:

“I say that in my opinion, a marked slide which is reviewed by an expert providing an opinion in a legal case in which negligent screening is alleged is not looked at in the same way as a slide [that] is routinely screened on initial presentation for screening, however hard the reviewer might try to do this. Reviewing a marked slide creates hindsight bias and is entirely different from screening an unmarked slide.”

“In my opinion, when it is the duty of care of the original screener/s which is being determined by the court then it should be screening of an unmarked slide which should be used to determine this and not a critical review of a marked slide”.

- (c) Ms. Cropper opines that the only way to avoid hindsight bias is to have the slide reviewed in precisely the same condition as it was originally reviewed by the cytoscreener(s) in 2010. That requires the removal of all markings. Ms. Cropper states that this is the only way in which to properly assess whether there was negligence on the part of the cytoscreener(s) who reviewed the slide in 2010. If all of the markings are not removed (both those applied by the cytoscreener(s) in 2010 and during the CAR in 2014) that creates a risk of hindsight bias. Ms. Cropper further opines at para. 9:

“Should the markings not be removed prior to presentation to a cytoscreener for expert review, it is my opinion that the cytoscreener will be subject to an inherent bias and that this would prejudice the way in which the slide is reviewed. In my opinion that in turn would severely prejudice any effort to mount a fair defence to this claim and would leave the Fourth Named Defendant at a serious disadvantage in that regard. I consider that the only way to remove this bias is to remove all the marks and present the slide to a cytoscreener in amongst a set of unmarked slides so as to replicate as best as possible the usual conditions of routine screening.”

- (d) Ms. Cropper sets out the manner in which the blind review would be conducted at para.s 9 and 12.
 - (e) Ms. Cropper explains at para.s 12 and 13 why she believes that the blind review which she proposes will not prejudice the plaintiff.
29. In her supplemental affidavit sworn on 5th Sept 2021, Ms. Cropper sets out, in the event of the order being granted, the manner under which the blind review would proceed involving 3 cytoscreeners and a process whereby none of them would be informed of the reason for the blind review of the unmarked slide. In her opinion, it is simply not possible to credibly create a blind review with marked slides.
30. In addition, Ms. Muldowney, solicitor for the fourth named defendant, states in her affidavit sworn on 19th July, 2021, that if the trial proceeds and CPL is not permitted to remove the markings from the slide, it will be significantly prejudiced in the presentation of its defence. In particular, she avers:
- “It will not be able to demonstrate through a cytoscreener review of an unmarked slide what conclusions were reasonably open when the slide was screened in [2010]. That exercise has a central significance to the issue of alleged negligence and the application of the principles in *Dunne v National Maternity Hospital* [1989] IR 91 and *Morrissey v HSE & Ors* [2020] IESC 6.”
31. No expert evidence was relied upon on behalf of the plaintiff in opposing the within application. Mr. O’Carroll, solicitor for the plaintiff, in his affidavit sworn on 23rd August, 2021, cites the potential prejudice to the plaintiff in the event of the court acceding to the application in circumstances where the removal of the markings would be tantamount to the destruction of critical evidence in the case.
32. However, it is clear that such prejudice was specifically addressed by the Court of Appeal where it observed that the destruction “does not in and of itself give rise to a conclusion that this is a reason, without more, for refusing an application...”.
33. Further, the plaintiff’s expert has already reviewed and imaged the slide with the markings on it so it is difficult to envisage what actual prejudice arises in circumstances where the work previously undertaken has been documented and preserved in digital format.

Discussion

34. In light of the evidence foregoing, I am satisfied that CPL has established a real risk of being put at a litigious disadvantage in the event of being denied the opportunity to carry out a blind review. Refusal of an order for the removal of the markings from the slide would undermine CPL's ability to replicate as closely as possible the manner in which the cytoscreener(s) would have reviewed the slide in 2010. Undoubtedly, the presentation of a marked slide to a cytoscreener compromises the integrity of a review. Hence, the inherent risk of hindsight bias as outlined by Ms. Cropper.
35. In the circumstances, it is evident that there is a real risk that CPL's defence to the proceedings may be prejudiced should the order be refused.
36. I must then consider whether there are any "compelling countervailing circumstances" which pertain which would militate against the granting of the order and in particular, whether there is any "demonstrable prejudice to the plaintiff". For the reasons already outlined I am not so satisfied.

Conclusion

37. In the circumstances, I will accede to the application granting liberty to remove the markings from the slide for the purpose of carrying out a blind review in line with the intended process as outlined by Ms. Cropper.