No. 1

O. 58, r. 15

SUPREME COURT

Record No:

Application for Leave to Appeal

Part I

The information contained in this part will be published. It is the applicant's responsibility to also provide electronically to the Office a redacted version of this part if it contains information the publication of which is prohibited by any enactment or rule of law or order of the Court

1. **Date of Filing:** 17 June 2019

2. **Title of the Proceedings:** *[As in the Court of first instance]*

RUTH MORRISSEY AND PAUL MORRISSEY

Plaintiffs

-v-

HEALTH SERVICE EXECUTIVE,
QUEST DIAGNOSTICS IRELAND LIMITED AND
MEDLAB PATHOLOGY LIMITED

Defendants

3. **Name of Applicant:** Quest Diagnostics Ireland Limited

What was the applicant's role in the original case: ***[Plaintiff, Defendant, Applicant, respondent etc]***

Second Named Defendant

4. Decision of Court of Appeal (where applicable):

Record No:

Date of Order: *Perfection Date:*

Date of Judgment:

Names of Judges:

5. Decision of the High Court:

Record No: *2018/4309P*

Date of Order: 24 May 2019 *Perfection Date:* 29 May 2019

Date of Judgment: 3 May 2019

Names of Judge(s): Cross J

Where this application seeks leave to appeal directly from an Order of the High Court has an appeal also been filed in the Court of Appeal in respect of that Order?

Yes [x] **No** [ ]

An appeal is being filed imminently in the Court of Appeal.

6. Extension of Time: **Yes** [ ] **No** [x]

If an application is being made to extend time for the bringing of this application, please set out concisely the grounds upon which it is contended time should be extended.

7. Matter of general public importance:

If it is contended that an appeal should be permitted on the basis of matter(s) of general public importance please set out precisely and concisely, in numbered paragraphs, the matter(s) alleged to be matter(s) of general public importance justifying appeal to the Supreme Court.

This section should contain no more than 500 words and the word count should appear at the end of the text.

1. These proceedings comprise an action for negligence in the context of screening for cervical cancer, an issue which has never previously been litigated before the Irish courts. The outcome of these proceedings will determine the standard of care for cervical cancer screening in Ireland. Cervical cancer screening is a key public health measure which is hugely effective in reducing rates of cervical cancer. The outcome of these proceedings will also most likely impact upon other forms of public health screening programs such as bowel and breast cancer as well as the standard of care in other branches of medicine.

2. The trial judge adopted a test for the standard of care in cervical cancer screening based on a concept of "absolute confidence." The trial judge incorporated this "absolute confidence" standard into the formal legal standard of care. The effect of this standard is that a cytoscreener who has any doubt that a slide is negative - however miniscule that doubt - is not entitled to categorise it as negative. The effect of this is to set a standard of care that is unachievable. Such a standard, therefore, poses a serious risk to the cervical cancer screening programme. The setting of such a standard is clearly a matter of general public importance.

3. The High Court judgment departs significantly from the principles set out in *Dunne v National Maternity Hospital* [1989] IR 91. For more than thirty years the *Dunne* principles have been universally regarded as setting the standard of care in clinical negligence in Ireland. These principles require that clinical actions are judged by reference to "general and approved practice" in the profession. If the clinical actions conform to such a practice, they can only be deemed negligent where they exhibit "inherent defects." The trial judge, in adopting the "absolute confidence" standard as part of the legal test, has fundamentally departed from the *Dunne* principles. Even where there is evidence that a cytoscreener has acted in accordance with a general and approved practice, he may be found negligent if he has not adopted the "absolute confidence" approach. This is the case, even if there is no suggestion that the practice is "inherently defective." Such a significant departure from the established principles of medical negligence is undoubtedly a matter of general

public importance.

4. The effect of the High Court judgment is to cast significant doubt on the ability of a cytoscreener to exercise judgment in the review of slides. Cervical cancer screening programmes operate on the basis of cytoscreeners, rather than pathologists, screening very large volumes of slides, the vast majority of which will be negative. Of those slides, only a small proportion will be passed on to a pathologist. If the cytoscreener must escalate all slides in respect of which he has "any doubt"- however miniscule-such programmes will swiftly become unworkable.

Word count – 473

8. Interests of Justice:

If it is contended that an appeal should be permitted on the basis of the interests of justice, please set out precisely and concisely, in numbered paragraphs, the matters relied upon.

This section should contain no more than 300 words and the word count should appear at the end of the text.

1. The Applicant submits that the general public importance criterion is satisfied in this case. In the alternative, it is submitted that the interests of justice criterion is satisfied.

2. Aside from the fact that this is a matter of general public importance, it is a matter of significant private importance to the Applicant. The Applicant is one of the principal providers of cervical cancer screening for Irish women. The test adopted by the High Court represents a significant departure from the *Dunne* standard, as described above. This was previously understood to be the applicable test in Irish law. The interests of justice require that the Applicant be entitled to determination of this issue by the Supreme Court.

~~3.~~ No prejudice will be suffered by the Plaintiffs through this issue being determined by the Supreme Court. Indeed it is also in the Plaintiff´s interests that this case be resolved as efficiently and decisively as possible.

Word count - 155

9. Exceptional Circumstances: Article 34.5.4:

Where it is sought to apply for leave to appeal direct from a decision of the High Court, please set out precisely and concisely, in numbered paragraphs, the exceptional circumstances upon which it is contended that such a course is necessary.

This section should contain no more than 300 words and the word count should appear at the end of the text.

~~1.~~ In the light of the considerable public importance of cervical cancer screening and in the light of the interests of the litigants herein, this is not a case in which an intermediate appeal would be valuable in terms of narrowing the issues to be determined between the parties. The issues between the parties were refined during the course of the High Court trial and those issues that remain are of great importance, and likely ultimately require to be determined by the Supreme Court.

~~2.~~ It is imperative that these proceedings reach a final determination as soon as possible. First, this is important from the perspective of cervical cancer screening in Ireland, where there is an immediate need for clarity on the "absolute confidence" standard. As set out above, other screening programmes and potentially other branches of medicine are likely also affected. Second, a speedy determination of these proceedings is in the interests of the Plaintiffs.

3. Third, the outcome of these proceedings will have a significant impact on other cases concerning negligence in cervical cancer screening. In respect of cases against the Second Named Defendant, 47 cases are issued and remain unresolved; one is set down for hearing. There are 79 other cases where a letter before action and/or legal correspondence has been received. All will be affected by the outcome in this case and all such cases are negatively affected by continued uncertainty as to the standard of care.

Word count – 242

10. Grounds of Appeal

Please set out in the Appendix attached hereto the grounds of appeal that would be relied upon if leave to appeal were to be granted.

11. Priority Hearing: **Yes** [x] **No** [ ]

If the applicant seeks a priority hearing please set out concisely the grounds upon which such priority is sought.

This section should contain no more than 100 words and the word count should appear at the end of the text.

It is imperative that these proceedings reach a final determination as soon as possible. First, this is important from the perspective of cervical cancer screening in Ireland, where there is an immediate need for clarity on the "absolute confidence" standard. Second, a speedy determination of these proceedings is in the interests of the Plaintiffs. The First Named Plaintiff is terminally ill.

Word count – 61

12. Reference to CJEU:

If it is contended that it is necessary to refer matters to the Court of Justice of the European Union please identify the matter and set out the question or questions which it is alleged it is necessary to refer.

Appendix

Notice of Appeal

1. **Title of the Proceedings:** *[As in the Court of first instance]*

RUTH MORRISSEY AND PAUL MORRISSEY

Plaintiffs

-v-

HEALTH SERVICE EXECUTIVE,
QUEST DIAGNOSTICS IRELAND LIMITED AND
MEDLAB PATHOLOGY LIMITED

Defendants

2. **Grounds of Appeal**:

Please set out in numbered paragraphs the Grounds of Appeal relied upon if leave to appeal were to be granted.

Ground 1: The Trial Judge Erred in his understanding and application of *Penney v East Kent Health Authority*

1. The learned trial judge purported to adopt the test as set down in *Penney Palmer v East Kent Health Authority,* but in fact adopted a different test which is significantly different to that because it incorporates an "absolute confidence" standard into the legal test. The trial judge adopted the three-stage test from *Penney Palmer*, as advocated by the Second Named Defendant in submissions. However, the trial judge added an additional element to that test that is not found in *Penney Palmer* in finding at §74 that:

> *The questions (ii) and (iii) above and any issues as to adequacy are to be decided in the light of the "absolute confidence" test and thereafter, the test for negligence is as stated in Dunne.*

2. Furthermore, the trial judge found as follows at §71:

> *I hold that "absolute confidence" is the screeners' practical duty in relation to their analysis of what is on the slide and indeed the adequacy of the sample, and the legal issue is whether or not they have carried out that duty in accordance*

with the Dunne principles.

3. The effect of these holdings is to formally incorporate "absolute confidence" into the legal standard. The trial judge erred in elevating this shorthand to a legal standard, thereby departing from the judgment in *Penney Palmer* with which he purported to agree. Furthermore, the trial judge erred in fact in his finding (at §70 and §85) that the Second Named Defendant and the Second Named Defendant's expert, Professor A, accepted and endorsed the "absolute confidence" test.
4. In the case of the interpretation of the 2009 slide by the Second Named Defendant, the application of the "absolute confidence" test as formulated by the trial judge and as applied to questions 2 and 3 identified in *Penney Palmer* led inexorably to a finding of negligence once the trial judge had answered question 1 being the question of fact as to what was to be seen on the slide. The High Court Judge's assessment of the crucial third question, namely whether a reasonably competent screener in the light of what he or she should have observed could have treated the slide as negative is confined to four paragraphs (§91 to §94), only one of which actually touches upon the substantive issue. In §93 the High Court Judge stated:

> *Accepting the absolute confidence tests, however, even on the basis of Mr. F's evidence e.g. "that there could have been other reasons for what we are seeing here", the absolute confidence test has not been met. As I stated above, I believe that the American screeners were utilising their professional skill and judgment and recording what they believed as a matter of probability was the case but that they ought not to have treated the slide as negative given the abnormalities as identified by Dr. McK*

This conclusion is reached by a simple application of the so-called "absolute confidence" test and without any application of the *Dunne* principles. Having found that they were as a matter of fact irregular cells to be seen on the slide, the application of the "absolute confidence" in this particular case test made the finding of negligence virtually inevitable.

Ground 2: The Trial Judge Erred in Adopting a Standard of Care that is Incompatible with Cervical Cancer Screening

5. In formally incorporating the absolute confidence standard into the legal test the trial judge adopted a standard that is incompatible with cervical cancer screening. All the evidence demonstrated that cervical cancer screening operates on the basis

of cytoscreeners, rather than pathologists, screening very large volumes of slides, the vast majority of which will be negative. Of those slides, only a small proportion will be passed on to a pathologist. Screening, therefore, depends on the judgment of the cytoscreener which enables him or her to make both a qualitative and quantitative evaluation of the cells they see on a slide, and ultimately to make a determination as to whether that slide is negative.

6. The test adopted by the trial judge nullifies the role of the judgment of the cytoscreener in the screening process, by requiring pathologist review of all slides in respect of which there is "any doubt", however miniscule.

Ground 3: The Trial Judge Erred in Misapplying and/or Departing From *Dunne v National Maternity Hospital*

7. The trial judge purported to apply the *Dunne* standard but in fact super-imposed a different test that fundamentally undermines and/or changes the *Dunne* principles.

The trial judge departed radically from *Dunne* by making a finding as to scientific best practice. He found as follows at §72:

> *In other words, if there is any room for doubt that the slide was normal and the screener ascribes a normal result to the slide then the screener is in breach of the Dunne principles as he has been guilty of such failure that no professional scanner of equally specialist or general status and skill would have been guilty of if acting with ordinary care.*

This finding was not legally supported by the *Penney* case or evidentially supported by the expert evidence in the present case.

8. Because of this erroneous finding, the trial judge did not consider the evidence of Mr F and Prof A through the prism of *Dunne* at all.

Ground 4: The Trial Judge Erred in failing to give adequate weight to the evidence of audits of the English cervical cancer screening programme

9. The trial judge failed to engage with the evidence as to the audits of the English cervical cancer screening programme and the logical effect that they must have on the appropriate standard of care. It was generally accepted by the experts in the present case that the English cervical screening programme is excellent. The trial judge recorded that, despite this, it was "*agreed that audits of patients who went on to develop cervical cancer who had been previously screened negative, found that, at least, 44% (or 55% depending on whether samples labelled as "inadequate" are*

counted) were incorrectly read at first screening." (§16)

10. The trial judge failed to appreciate that this evidence must mean that the absolute confidence standard a) is unworkable and inappropriate and b) is not actually applied in cervical screening programmes that are undeniably excellent yet have a 45-55% false negative rate.

Ground 5: The Trial Judge Erred in Failing to give any or any adequate weight to the Evidence as to Retrospective or Hindsight Bias

11. The evidence demonstrated that the practice of cytology is particularly susceptible to hindsight bias and that this must be addressed in assessing the decision of a cytoscreener as to whether a slide is negative. The Second Named Defendant led evidence from Professor Neal Roese on this point but the trial judge expressly refused to give any weight to that evidence. He stated that the court did not need to be informed on the issue by a "learned professor of psychology". (§75) The trial judge erred in failing to give the evidence of Prof Roese any weight whatsoever, and then failing to take steps to ensure that the problem of hindsight/retrospective bias was addressed in the Court's approach to weighing the evidence.
12. The trial judge erred in mischaracterizing hindsight bias as being a concept that is causally connected to professionalism, or a lack thereof, by a post facto reviewer, (§18).

Ground 6: The Trial Judge Erred in Failing to Give Sufficient Weight to the Evidence based on Blinded Review

13. The judge failed to give sufficient weight to the evidence as to the blinded review of the 2009 slide carried out by Mr F. The trial judge further failed to provide sufficient reasons for his refusals to accord sufficient weight to this evidence, and further erred in adverting to "hazards" of blinded review (§76) without engaging with what those alleged hazards were or with the response of the Second Named Defendant's witnesses to those alleged hazards.
14. The trial judge further erred in this regard by failing to give adequate weight to the fact that Ms T accepted that blinded review provided the fairest evidence as to the behaviour of a reasonably competent cytoscreener.
15. The trial judge further erred in this regard by failing to give any or adequate weight to the use of blind review by the UK Royal College of Pathologists in assessing professional competence by its members.

Ground 7: The Trial judge Erred in Failing to Give More Weight to the Evidence of the Cytoscreeners than to Pathologists in relation to the Reasonably Competent Cytoscreener

16. The trial judge's conclusions are to a very significant degree based on the evidence of Dr McK. Dr McK is a pathologist, not a cytoscreener. The case concerned the standard of care of the reasonably competent cytoscreener. On the facts of this case, the best evidence of this was from a cytoscreener. In this instance, the evidence of a pathologist was not irrelevant, but should have been accorded less weight than that of a cytoscreener.

Ground 8: The Trial Judge Erred in Its Findings as to the Reliability of The Second Named Defendant's US Witnesses by Reference to the ASC Guidelines

17. The Trial Judge erred in concluding that the evidence of Prof A, and the US witnesses more generally, was unreliable because of the Guidelines of the American Society for Cytology, to the effect that most cases of ASCUS or AGUS *"do not represent consistently identifiable abnormalities and a reasonable basis for allegations of a practice below a reasonable prudent practitioner's standard of care."* (§60) The mere existence of the said Guidelines has no bearing on the ability of Prof A to identify ASCUS/AGUS or on whether he would believe an error in this regard to have been acceptable on the part of a reasonably competent cytoscreener.

18. As regards Mr F, in evidence he expressly disagreed with aspects of the Guidelines, and thus the trial Court's findings cannot be sustained. The trial judge further erred in characterizing the evidence of Prof A and Mr F. Their evidence was that they believed blinded review to be the fairest form of assessment. Rather than a distorting *a priori* bias, this view was a sincerely held professional opinion, which is entirely appropriate for an expert witness. Indeed, the Plaintiff's expert witness, Ms T, did not disagree with this view.

Ground 9: The Trial Judge Erred in Mischaracterising and Failing to Give Sufficient Weight to the Evidence of Mr F

19. The trial judge erred in finding that Mr F applied a balance of probabilities standard in reviewing the slide. In fact, Mr F's evidence was that he required a high degree of certainty, but he expressed discomfort as a scientist with the concept of "absolute confidence". The trial judge further failed to give weight to Mr F's evidence that he considered ASCUS to be a very important category, and that this was the case in US cytology generally, and that in the blind review that he coordinated, he included

ASCUS and AGUS as categories that should be reported, and indeed ASCUS and AGUS were identified by his screeners in multiple cases in that blind review.

20. The trial judge erred in finding that the Second Defendant's cytoscreeners applied a balance of probabilities standard in reviewing the slide. No evidence was advanced to this effect. All experts, plaintiffs and defendant, gave evidence that a screener must be (at least) confident that a slide was normal before calling it normal.

Ground 10: The Trial Judge Erred in Refusing to Admit Evidence as to Blinded Review by a Pathologist

21. The Trial Judge erred in refusing to admit expert from an additional expert witness for the Second Named Defendant. On 15 February the Second Named Defendant made an application to be allowed call evidence from a pathologist who had carried out a blinded review of the 2009 slide. The said applicant was based upon a very recent development in the case whereby it was determined that the green marking of which the Plaintiff's expert had complained had been removed by persons unknown thereby facilitating a blinded review of the slide by a pathologist without the green markings.
22. The application was refused by the Trial Judge on the basis that the evidence sought to be called would involve a duplication of the evidence that the Second Named Defendant had already had led. The Trial Judge found that if he were to allow the evidence, he would be allowing:

> *... somebody else to say the same thing; the witness is not here principally to discount the evidence of Dr. McK, that the blind review system is a bad system or is a necessary system; he is here just to give his view as to the slide having examined it on its own and I think that that falls into a multiplicity of experts saying essentially the same thing and I am not going to allow it.* (15 February, p 136)

23. The Trial Judge erred in this conclusion. By reason of this ruling, the Second Named Defendant was deprived of the opportunity to lead any evidence of blinded review by a pathologist which unfairly and significantly limited its ability to meet the Plaintiffs' case.

Ground 11: The Trial Judge Erred in Failing to Give More Weight to and/or Admit the Best Evidence as to What Was to Be Seen on the Slide

24. The trial judge failed to give greater weight to the best evidence of what was to be

seen on the slide. The trial judge accorded too much weight to evidence based on Dr McK's second report, which was based on a photograph of the slide rather than on examination of the slide. Dr McK's first report was based on direct examination of the slide and was therefore the better evidence.

25. The trial judge further erred in refusing to allow Dr A to give his evidence on the slide through the use of an in-court microscope and screen. It was agreed by the experts – and commented upon by the trial judge himself – that the quality of what one can see on a slide using a microscope is far higher than what one can see from a photograph. In placing undue reliance on photographs of the slide, the Court fundamentally erred and deprived itself of the best evidence.

Ground 12: The Trial Judge Erred in Finding that the Plaintiffs had Established Causation in Respect of the 2009 Slide

26. The Trial Judge erroneously found that the Plaintiffs proved on the balance of probabilities that but for the misreading of the 2009 slide, the Plaintiff would not have suffered the damage alleged.
27. The Trial Judge failed to give adequate weight to the evidence that cervical cancer behaves more aggressively in some younger women, suggesting that neither squamous pre-cancer, nor squamous abnormalities were present in 2009. The Second Named Defendant led substantial evidence of academic literature demonstrating that cervical cancer moves more quickly in some younger women, which the Plaintiffs never addressed, and the trial judge failed to consider in adequate detail.
28. The Trial Judge further erred in finding on the balance of probabilities that the existence of abnormal (glandular) cells in 2009 indicated the presence of squamous abnormalities. The evidence of Professor Wells and Prof Shepherd did no more than establish the possibility of such coexistence, not the probability of same, whereas the Trial Judge considered such co-existence 'highly likely'.
29. He further erred in finding that the existence of abnormal (glandular) cells in 2009 must mean that cancer (or pre-cancer) was present also. All experts gave evidence that abnormal glandular cells are not pre-cancer, which the Trial Judge accepted elsewhere in his judgment: *"the borderline categories of ASCUS or AGUS do not themselves denote either cancer or pre cancer but do represent a non-negative finding and require at least repeat smears or colposcopy"* (§9).
30. Further, the Trial Judge erred in law and in fact in adopting the unfounded

hypothesis that had the First Plaintiff undergone a repeat smear in 2009 it would have shown abnormal cells, particularly in the context of the 2012 smear that did not show the presence of any cancer or pre-cancer, the normal 2014 smear, which was taken *after* the First Plaintiff's cancer diagnosis and the 2014 trachelectomy specimen which showed limited CIN3, and no evidence of glandular cancer or precancer. In combination with the evidence as to the 2009 slide, the 2012 slide, the 2014 slide and the 2014 trachelectomy specimen, the evidence led by The Second Named Defendant meant that the Plaintiffs did not prove causation on the balance of probabilities.

Ground 13: Findings on Inter-Defendant Liability

31. Having found the Defendants to be jointly and severally liable, the Trial Judge Erred in making any finding as to the apportionment of liability as between them, whether as a matter of contract or otherwise. Such matters were not in issue between the parties and were not addressed by them in evidence or submissions. When the trial judge enumerated the matters to be addressed in submissions in the course of the trial, he made no reference to issues of inter-defendant liability. (15 February 2019, p178-179)

3. Order(s) sought

Please set out in numbered paragraphs the order(s) sought if the Appeal were to be successful.

1. An order setting aside the High Court judgment and orders.

2. If necessary, an order directing a full retrial in respect of all elements of the Plaintiffs' claim.