Neutral Citation Number: [2024] EWHC 1071 (TCC)

Claim No. HT-2022-000141

IN THE HIGH COURT OF JUSTICE
BUSINESS AND PROPERTY COURTS OF ENGLAND AND WALES
TECHNOLOGY AND CONSTRUCTION COURT (KBD)

The Rolls Building
7 Rolls Buildings
Fetter Lane
London EC4A 1NL

Date: Tuesday, 30th April 2024

Before:

MRS. JUSTICE JEFFORD

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Between:

SECRETARY OF STATE FOR HEALTH AND SOCIAL CARE — **Claimant**

- and -

(1) PRIMER DESIGN LIMITED
(2) NOVACYT S.A — **Defendant**

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MR. ADAM HEPPINSTALL KC, MS. LUCY McCORMICK and **MR. GEORGE MALLET** (instructed by **The Government Legal Department**) appeared for the **Claimant.**

MR. ANDREW TWIGGER KC and **MR. JONATHAN ALLCOCK** (instructed by **Stephenson Harwood LLP**) appeared for the **Defendants.**

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Approved Judgment

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MRS. JUSTICE JEFFORD :

Background

1. This is the pre-trial review in relation to the claim of the Secretary of State against the First Defendant, Primer Design, and he Second Defendant, Novacyt, which provided a guarantee in respect of the performance of a contract entered into between the Secretary of State and Primer Design on 28th September 2020. The contract was for the supply of 6,300 Exsig COVID-19 testing kits per week for an initial period of 14 weeks. With the supply of other equipment the total value of that contract was £175 million.

2. It is common ground that the contract contained the express terms of the so-called Limited Warranty. That warranty included a warranty that each reagent kit should be of good quality and free of material defects and function in accordance with the Specification. It is common ground that the Specification was version 1 of Primer Design's Exsig IFU (or Instructions for Use).

3. As originally pleaded, the Particulars of Claim alleged three breaches of contract and three breaches of the Specification relating to sensitivity of the testing, use with oropharyngeal specimens and use with PBS nasal swabs.

4. In November 2022, the Particulars of Claim was amended to add a further breach at paragraph 37(D) of the Particulars of Claim. That is in the following terms:

> "It is averred that during TVG validation over half of the Exsig Kits reported a Cq number of more than 27. PD's IFU advised users to only use tests where IEC (Internal Extraction Control) Cq result is less than 27. The fact that over half of the apparent false negative results reported Cq numbers of more than 26 is further evidence that the assay was flawed and lacked robustness. This fact is further highlighted when the true negative results are also examined as large numbers of those results also returned an IEC Cq result of greater than 26. That a significant number of invalid results was noted across different sites demonstrates that the assay was flawed and not sufficiently robust for use. As such, it was in breach of the Specification as set out in paragraph 14 above, in that it did not perform to the standards reasonably to be expected of a laboratory based in vitro diagnostic device capable of detecting the SARS-CoV2 virus. Further or alternatively, for the same reasons, the Exsig was not of good quality nor free of material defects ...".

The paragraph went on to allege that public safety would have been imperilled by a large number of invalid test results.

5. As I understand it, and expressed it during the course of argument in layman's terms, the Internal Extraction Control, IEC, is a provision within the test kit to test for genetic material which is wholly unrelated to the Covid virus. If that is not identified within 26 cycles of the test, the test is considered invalid. The IFU at section 15 states

that if the IEC is not detected, or is detected on the 27th cycle or later, this "indicates a compromised sample preparation and an invalid result".

6. The claimants infer from the number of invalid tests that there was a flaw in the reagent kits; that they were not sufficiently robust for use, that is that they failed to produce valid results at an acceptable rate; and that they did not, therefore, perform to the standards reasonably to be expected of a lab-based in vitro diagnostic device for the virus and were not of good quality. The claimants say that that is a breach of the warranty of good quality and/or the warranty in respect of performance in accordance with the Specification.

7. The first defendant, Primer Design, puts in issue, first of all, the construction of the warranty. In summary, and without in any way committing the defendants to this summary, Mr. Twigger KC submits that the warranty of good quality relates only to the condition of the reagent kits and not to their performance, or the performance of the Exsig kit as a whole, and that the warranty in respect of the specification is that the kits, or the elements of the kits, will perform in accordance with the Specification if the Instructions for Use are followed. He submits that the Instructions for Use are detailed and specific.

8. As to the case on robustness more generally, the defendants say that there is no contractual requirement of robustness which is itself a vague term. The IEC has been designed to detect a compromised sample and invalid result and, therefore, an "IEC failure" cannot evidence a flaw in the test kit. On the defendants' case, it follows that the claimant needs to show why the rate of invalid test results was the product of a flaw in the kits themselves and not an external factor.

9. That is a high level summary of the dispute between the parties and a high level summary of the dispute that is relevant to the applications before me.

Directions and the experts' joint statement

10. A case management conference was held on 27th January 2023 and directions given by O'Farrell J. As is the usual practice in the Technology and Construction Court, the experts were directed to meet on a without prejudice basis before the exchange of their reports. The purpose of that direction is that it encourages experts to express independent opinions without any concern that they are departing from what they have already committed to writing in their reports, and that their reports will then be limited to the matters which are still in dispute. Although that ought to encourage briefer reports, experts not uncommonly end up explaining what they have agreed and why. Sometimes that is genuinely necessary in order to enable the court to understand the effect of the agreements that they have reached, or to explain the areas of disagreement that remain. Sometimes it is, at best, unnecessary and, at worst, confusing. Which is it is necessarily case specific.

11. In this case, time for service of the experts' reports, limited to the expert issues remaining in dispute, was 5.00pm on 15th March 2024. Provision was made for the experts to attend trial if they were not in substantial agreement on all matters. It is relevant to the decision that I have reached that both parties, in my view, have taken an excessively literal approach to that direction, and it has resulted in a highly unsatisfactory position at this pre-trial review.

12. In this case, the experts are, for the claimant, Dr. Jim Huggett, Science Fellow and Director of Biological Metrology at the National Measurement Laboratory in Twickenham, and, for the defendants, Dr. Marilyn Owens of Medical Laboratory Strategy & Leadership, Sundance, Wyoming. I have been told that both experts are, at least in this jurisdiction, first time experts, and that is hardly surprising given the particular subject matter on which they have been asked to express their opinions.

13. The parties agreed a high level list of issues for the experts to address. They met without prejudice as directed to address those issues and produce their joint statement dated 15th February 2024, which recorded a very substantial measure of agreement and only one area of disagreement.

14. On 23rd February, the defendants' solicitors wrote to the claimant setting out their concerns about the joint statement and, amongst other things, that the experts had gone beyond their remit and in doing so had proceeded on the basis of findings of fact which they were not entitled to make or incorrect views of the facts or incorrect assumptions as to the facts. They said that they elected not to be bound by the joint statement, following Part 35.12(5), and intended to ask Dr. Owens to produce a report on all matters, whether agreed or not agreed on the face of the joint statement, and they asked for an extension of time to the end of March for exchange.

15. That was not acceded to. Dr. Huggett's report on the limited matters not agreed was filed on 15th March, 2024. No report from Dr. Owens was or has been filed.

The defendants' application

16. Instead, on 15th March 2024, the defendants made an application to the court for an extension of time to the 3rd May to serve expert evidence and for that evidence to extend to matters agreed and not agreed. Although this pre-trial review has brought to light a discrepancy between the date when the parties thought this trial was to commence and the date in the court diary, which has fortunately been addressed, that date of the 3rd May has to be seen against the context that the parties had already been directed to provide their opening submissions by the 24th May, that they expected the court to be reading from the 3rd June and expected the trial, in the sense of the hearing, to commence on 10th June. I shall return to that in a moment.

17. The application made on the 15th March was an in time application, not an application for relief from sanctions as the claimant at one point appeared to contend, but, in my view, no satisfactory explanation has been offered for why a report was not filed, if not by that date, by a later date and before this hearing, so that the claimant and the court could know what the scope and relevance of the report that the defendants wished to file was, or wished to rely on was. This is particularly so where the defendants positively said in the application notice that they wanted to have this application heard at the PTR.

18. Mr. Twigger submitted that it would not have been helpful, as I suggested, to ask the experts to meet again and reconsider their position in the light of the defendants' view as to or issues with the factual assumptions and findings they said the experts had wrongly made. He submitted that the underlying problems with the experts' approach to the facts in the joint statement were so complex that that would have been an unhelpful approach. He also submitted that if Dr. Owens' report had been served, it

would have meant that the defendants went first, and then, assuming the court gave permission for a further report, Dr. Huggett would have responded already knowing what Dr. Owens was going to say. Neither of those submissions seems to me to provide a proper explanation for the absence of any report from Dr. Owens or for why this matter has been left to be addressed at the pre-trial review five weeks before the start of the trial. I refer again to the dates that I mentioned a moment ago.

19. Had the defendants served a report which elaborated on what had been agreed, and perhaps addressed the underlying assumptions which the defendants say are wrong in fact, there could have been a sensible review at the pre-trial review and/or at trial as to how much of that report was helpful to the court, bearing in mind the terms of the order on the CMC, but also bearing in mind that that was not somehow writ in stone. Instead, the approach has been to serve no report at all on the basis that a report which addresses matters agreed as well as not agreed does not comply with the order of O'Farrell J and to wait until the pre-trial review to make the application which is now before me.

The claimant's application

20. The claimant's response to the defendants' application was to make her own application on 21st March 2024 seeking summary judgment on a claim for over £130 million, on the basis that the experts agreed that Exsig failed at an unacceptable rate and, therefore, lacked robustness so that the claimant's case on breach was made out and the defendants' defence on this alleged breach had no real prospect of success. Again, determination of that application was left until the pre-trial review.

21. The claimant relies on a number of passages in the joint statement of the experts which I will paraphrase. The passages are to the effect that if the IEC is not detected it suggests that there is something wrong with the reaction and, consequently, a negative Covid result should not be trusted, the run considered invalid and the test repeated. With the exception of Portsmouth, all laboratories had a more than 10% failure rate, with four laboratories experiencing greater than 25% invalid runs which would indicate, the experts said, that the Exsig COVID-19 test was not sufficiently robust.

22. They referred to the WHO Guidelines that stated that an acceptable criterion for invalid results in point of care tests should be less than 2%. They provided in Figure 2 in the joint statement a graphical illustration of the number of invalid test results and said that they were not aware of any standard where the failure rate outlined in Figure 2 would be considered acceptable for a diagnostic test.

23. Most particularly, towards the end of the joint statement, they said this:

> "However, the technical failure rate of the TVG study data indicated a significant problem with the method's robustness. The conclusion of the findings from the seven laboratories are further supported by e-mails from Novacyt (PD) (both internally and to NHS laboratories) illustrating steps to rectify what they admit was an issue due to run failures (namely how the optimiser was dispensed and the revoking of software update v 2.7 fast cycling protocol with 2.10.01). This suggests the exsig COVID-19 Direct was not working as intended and

> that the IFU protocol and software updates were more to blame than the NHS laboratory staff, who were running other diagnostic tests on a routine basis. However, it is not clear if the potential improvements were implemented by all the NHS laboratories."

24. Importantly, as I understand it, the claimant contends that the agreed lack of robustness evidenced in those statements and others in the joint statement is itself sufficient to establish a breach of contract, that is that the Exsig kits are not of good quality and free from defects, irrespective of the underlying cause of that lack of robustness.

25. Although I do not propose to repeat them here, in Mr. Heppinstall KC's skeleton argument a number of authorities are cited for the over-arching proposition that it is necessary only to establish the existence of a defect and not the cause of the defect in order to establish a breach of contract.

26. The defendants say that that contention is not relevant in this case. I have outlined the nature of the defendants' case including that there is no contractual requirement of robustness and that it is a meaningless or vague term which is the subject of two further definitions in the joint statement which differ from the pleaded case. The defendants, as I have indicated, also say that the rate of invalid test results does not evidence a flaw in the kits themselves and/or that the kits were not of good quality.

27. Returning to the last passage that I set out from the joint statement, the defendants submit that kits may not have worked as intended because of what the experts refer to as the IFU Protocol, software updates and performance of NHS staff. In other words, the testing may have lacked robustness for reasons other than the kits themselves.

28. If the cause of IEC failures was software updates, those, Mr Twigger says, are not encompassed by the terms of the Limited Warranty. If the cause was performance of NHS staff - albeit the experts' conclusion is that the protocol and software updates were more to blame than the laboratory staff - that is also not something for which the defendants are responsible. I do not propose to repeat the entirety of Mr. Twigger's submissions, both in writing and orally, but he also points to a number of other possible causes of invalid tests which are referred to in the joint statement.

29. Mr. Twigger says that the reference to the IFU Protocol is itself unclear. It does not appear to refer to the Instructions for Use, which is not a protocol, and seems to refer to other protocols which were the subject matter of e-mail exchanges which the experts refer to in other passages in the joint statement.

30. As to the reference to the IFU Protocol in the passage I have quoted, Mr. Twigger suggests that the experts seem to be referring to the step in the Instructions for Use which involves the pipetting of two microlitres of PCR optimiser. He says that the experts appear to assume that the optimiser is difficult to pipette in such small quantities because of its viscosity but that that is based on a misconception that it was a viscous liquid. If it is not in fact a viscous liquid, it is not difficult to pipette in that small quantity, and if staff had a difficulty in pipetting it, that would be a human error and not evidence of any lack of robustness in the testing kits.

31. The claimant's answer to what I might call the human error point – and there are other examples of potential human error -- is Figure 2 in the joint statement and which shows a level of invalid results which the experts say could not be acceptable. The claimant argues that that in itself demonstrates that the invalid results must be the result of a flaw in the kits and not human error.

32. The defendants say not only that that is a factual inference that cannot properly be drawn but that Figure 2 does not support it. For example, it can be seen that one site at Portsmouth had no invalid test results, which itself suggests that there was nothing wrong with the kits and that invalid test results were or might have been the product of human error.

33. Those points, and they are a summary of the detailed submissions that have been made to me, are sufficient for me to conclude that I cannot say, on a summary basis, that the defendants have no real prospect of success on this issue of robustness, despite the apparent level of agreement of the experts. I decline to grant summary judgment on this issue or this claim as a whole. It may be, at trial, that the claimant succeeds on this basis, but it would be wrong to reach that conclusion at this stage, solely on the basis of the joint statement and without fuller consideration of the defendants' case, the factual evidence, the documentary evidence and the matters that Mr. Twigger has advertised.

Directions in respect of expert evidence

34. That leaves the issue of the Order in respect of expert evidence. In written submissions, the claimant argued that it was not open to the defendants to adduce a full report of Dr. Owens, covering matters both agreed and not agreed, because there was no evidence that she had altered her expressed opinion from that in the joint statement and there was no application to adduce the evidence of a new expert for some legitimate reason.

35. The claimant also says that the defendants missed their opportunity to ask the experts, that is both experts, to address further issues or consider further evidence so that their agreement did not mislead the court, reflecting paragraph 13.6.3 of the TCC Guide.

36. In my judgment, these submissions are more submissions about the utility of any further report from Dr. Owens. The order on the CMC was that the report should be limited to matters not agreed but that was not writ in stone and it is not uncommon for reports to provide further information, sometimes helpful, sometimes unhelpful, as to the basis on which agreements were reached.

37. The defendants make out a tenable case that the joint statement does not address all the issues that it should, or proceeds on the basis of underlying factual assumptions made the experts or conclusions reached by them which are either wrong or open to challenge or examination at trial. The issue, however, is whether a further report of Dr. Owens would be of assistance to the court in addressing those issues, and/or whether that would put the claimant at such a disadvantage at this late stage that it would be wrong, having regard to fairness between the parties and the furtherance of the overriding objective, to permit the defendants to rely on such a report.

38. On balance, it seems to me that it would be more helpful to the court and more efficient if such a report were to be served. If there were no such reports, it would still be open to the defendants to cross-examine Dr. Huggett on these matters without the court having the benefit of the views of both of the experts on these matters, and the value and helpfulness of Dr. Huggett's evidence in cross-examination is likely to be diminished.

39. In that context, it is of some concern to me that, on the face of Dr. Huggett's report on the limited issue remaining in dispute, he appears to have considered a limited number of documents set out in Annex 1 to his instructions which appears to have been provided to him before the amendments to the Particulars of Claim. He lists out the full scope of the documents he has referred to which do, however, include the amended pleadings. It is self-evident that he has seen those from the context of the joint statement but it is not self-evident that he has seen all the documents that he ought to have seen.

40. Even without that concern, Mr. Twigger has taken me to e-mails relied upon by the experts to reach certain factual conclusions, which are then relied upon as supporting their views on robustness. He clearly has an arguable case that he can put to Dr. Huggett that the interpretation of these e-mails is wrong, and Dr. Huggett may be invited to express his views on an alternative basis. However, as I have already said, if that were to be done for the first time in cross-examination, it would be done without any notice to him as to the matters that were likely to be raised and any opportunity to consider them and formulate his response. That would not be in the interests of fairness and justice as between the parties.

41. If the defendants' application had come before me promptly after 15th March 2024, I would have allowed it without hesitation. The difficulty now is that it is being determined five weeks before trial, and that what I have said about fairness and justice as between the parties may be rather different five weeks before the trial from what it would have been six weeks ago.

42. In written submissions, Mr. Heppinstall submitted that if Dr. Huggett is now required to produce a full report that will derail the trial and necessitate an adjournment. In oral submissions he has said it would be wholly unfair to the claimant to require Dr Huggett to produce a report at such short notice. However, if I allow the defendants to adduce a report of Dr. Owens, that would be equally unfair if Dr. Huggett had no opportunity to respond.

43. The defendants' response to the claimant's unfairness point is to be found in Mr. Smith's statement dated 15th March 2024. He made it clear in that statement that this application in relation to expert evidence would be dealt with at the pre-trial review, which was then fixed for 26th April but, for listing reasons, has taken place a few days later. He indicated that the defendants would be ready to serve Dr. Owens' report on the 3rd May 2024. He further makes the point that the claimant had been on notice of the defendants' position since the letter of the 23rd February 2024 and that it was open to them to instruct Dr. Huggett to prepare a further report in a time period that corresponded to that afforded to Dr. Owens.

44. It is probably clear from what I have said already that, in mu view, a far better approach would have been either to ask the court to hear this application as soon as

possible, rather than leave it to the pre-trial review, and/or to provide Dr. Owens' report in any event with any argument as to the scope that it properly covered to be dealt with at the pre-trial review or at trial. However, on the other side of the coin, it seems to me that what the claimant has done is proceed on the basis that the defendants' application was bound to fail, or that summary judgment was bound to be entered, so that she could postpone any further instructions to Dr. Huggett until after this hearing. That was an unrealistic approach. Given the size of this claim, there could have been no objection to further expenditure on expert evidence and consideration at least of the issues raised in Stephenson Harwood's letter and Mr. Smith's statement - not least because it could be anticipated that those issues would be raised with Dr. Huggett at trial, even if no further report of Dr. Owens was permitted.

45. In conclusion, although it is far from a satisfactory position, it seems to me that the fair and efficient way to deal with this matter at this stage, without prejudicing the trial date, is to grant the defendants' application and then to give the claimant a further two weeks in which to serve a further report of Dr. Huggett. They will therefore be sequential reports, but it will enable Dr. Huggett to respond to the matters which it now appears will be raised by Dr. Owens so that their reports do not pass as ships in the night. There will be nothing to prevent them discussing matters further, reasserting the agreement they have already reached (if, as no doubt the claimants would anticipate, there is no change in either experts' view), or modifying them to the extent appropriate.

46. Accordingly, I refuse the application for summary judgment; I allow the defendants' application in relation to Dr. Owens' report, to be served by 3rd May; and I provide for Dr. Huggett to serve a further report in response by 17th May.

47. As to the attendance of the experts at trial, I think the practical approach to that is to assume they will attend trial and will be available for cross-examination, but should they reach further agreement which means that this position changes that can be addressed at the start of the trial.

Further factual evidence

48. That leaves one further matter on which I have not been specifically addressed, namely the third statement of Dr. Birnie. I have read that statement. It does, I think, veer into areas of opinion, but that is a matter that I can take into account in terms of the weight of the evidence when it comes to trial. The principal reason for relying on that evidence is to refute the suggestion that the optimiser is a viscous liquid and it seems to me that at this stage before trial it is entirely proper that that issue, which the defendants say with some justification they had not anticipated having to address, should be addressed by the further short statement that they wish to rely on. I will give permission for them to do so at trial.

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