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Case No: BL-2021-002193

IN THE HIGH COURT OF JUSTICE
BUSINESS AND PROPERTY COURTS
OF ENGLAND AND WALES
CHANCERY DIVISION

Rolls Building
Fetter Lane
London, EC4A 1NL

5 April 2023

Before :

MR JUSTICE RICHARDS

Between :

ASTRAZENECA UK LIMITED

Claimant

- and -

TESARO, INC.

Defendant

Alan Maclean KC and Katherine Moggridge (instructed by **Freshfields Bruckhaus
Deringer LLP**) for the **Claimant**
Tom Mitcheson KC, Conall Patton KC and Georgina Messenger (instructed by **Linklaters
LLP**) for the **Defendant**

Hearing dates: 3 (reading), 6 to 8 and 10 March 2023

Approved Judgment

**I direct that no official shorthand note shall be taken of this Judgment and that copies
of this version as handed down may be treated as authentic.**

This judgment was handed down remotely at 10am on 5 April 2023 by circulation to the parties or their representatives by email and by release to the National Archives.

Mr Justice Richards:

1. The Claimant (“AZ”) is the head licensee of certain patents (the “Licensed Patents”) under agreements (the “Head Licence Agreements”) with the holders of the Licensed Patents, namely the Institute of Cancer Research (“ICR”) and the University of Sheffield.
2. AZ has entered into sub-licence agreements (the “Licence Agreements”) of the Licensed Patents with the Defendant (“Tesaro”). These proceedings concern the interpretation of the royalty provisions of the Licence Agreements. By way of very broad overview, AZ contends that the Licence Agreements require Tesaro to pay a royalty calculated by reference to total sales of relevant products for use as cancer treatments (i.e. that there is a “total sales royalty”). Tesaro argues that the royalty is payable only on sales that are for uses claimed or covered by the Licensed Patents.
3. The parties have helpfully agreed a list of issues. I will not set out that list in full not least because, by order of Deputy Master Arkush of 26 May 2022, only Issue 1, which concerns the proper construction of the royalty provisions of the Licence Agreements, falls to be determined in the proceedings before me. However, that question of construction involves the determination of seven questions of fact (described as Issues 1.1 to 1.7 on the parties’ list) and I will address those issues throughout this judgment.

EVIDENCE

4. AZ relied on no evidence from witnesses of fact, but relied on expert evidence from:
 - i) Mr Thomas Hoxie, an attorney, a patent attorney and an English-qualified solicitor. Mr Hoxie’s evidence was relied on largely as regards the scope of the claims made in the Licensed Patents granted in the US and matters of US patent law.
 - ii) Mr Glen Belvis, a practising attorney and patent attorney. Mr Belvis’s evidence was relied on largely as regards the US law concept of “patent misuse”.
5. Tesaro relied on factual evidence from Mr Leon Moulder, who was Tesaro’s chief executive from the time of its formation in 2010 until after the execution of the Licence Agreements in 2012.
6. Tesaro also relied on expert evidence from the following:
 - i) Judge Kathleen O’Malley, a retired judge of the US Court of Appeals for the Federal Circuit. Judge O’Malley’s evidence was relied on as regards various matters of US patent law, including the doctrine of patent misuse.
 - ii) Dr Jonathan Krell, an oncologist and consultant and senior clinical lecturer at Imperial College London. Dr Krell’s evidence was directed mainly at

oncological matters including conclusions that an oncologist might draw from reading the specification and claims of the Licensed Patents in 2012.

7. Mr Moulder was quite clearly an honest and reliable witness and it was not suggested otherwise. I have accepted the evidence that he gave.
8. Both sides made criticisms of each other's experts. However, I have concluded that, even though they had very different ways of giving their oral evidence, all experts were conscious of their duties to the court and sought to assist the court with their expert evidence.
9. I have, however, concluded some parts of the expert reports of both Mr Hoxie and Mr Belvis were inadmissible. That does not involve any criticism of either Mr Belvis or Mr Hoxie since the problem was not that they strayed outside their expertise in the relevant passages, but rather they strayed outside the scope of the permission to rely on expert evidence that Deputy Master Arkush had granted. I will explain which aspects of their respective expert reports were inadmissible later in this judgment and for the time being I simply note that I have put those passages out of my mind.

THE RELEVANT LAW

The interpretation of contracts

10. There was no substantial dispute between the parties as to the principles that I should apply when construing the Licence Agreements which are governed by English law.
11. The parties agree that no special rules of English law apply to a patent licence. Therefore, the general principles summarised below apply to patent licences just as to any other contract.
12. Given the absence of a dispute on the applicable principles between the parties, there is no need for me to engage in a detailed analysis of authorities such as *Rainy Sky S.A. v Kookmin Bank* [2011] UKSC 50, *Wood v Capita Insurance Services Ltd* [2017] AC 1173 and *Arnold v Britton* [2015] UKSC 3, although I have borne well in mind the principles set out in those authorities. Nor do I need unnecessarily to lengthen this judgment with unnecessary quotes from authorities whose principles are not in dispute.
13. For present purposes, the simple distillation of the applicable principles given by Carr LJ in *ABC Electrification Ltd v Network Rail Infrastructure Ltd* [2020] EWCA Civ 1645 provides a neat introduction:

When interpreting a written contract, the court is concerned to identify the intention of the parties by reference to what a reasonable person having all the background knowledge which would have been available to the parties would have understood them to be using the language in the contract to mean. It does so by focussing on the meaning of the relevant words in their documentary, factual and

commercial context. That meaning has to be assessed in the light of (i) the natural and ordinary meaning of the clause, (ii) any other relevant provisions of the contract, (iii) the overall purpose of the clause and the contract, (iv) the facts and circumstances known or assumed by the parties at the time that the document was executed, and (v) commercial common sense, but (vi) disregarding subjective evidence of any party's intentions;

14. In the present dispute, Tesaro places more reliance on factual background than does AZ. Tesaro therefore asks the court to draw certain inferences from relevant factual background as to the correct interpretation of the Licence Agreements which AZ considers either should not be drawn or are displaced by other indications to be found in the words of the Licence Agreements themselves. Given the dispute of that kind, I will supplement Carr LJ's summary with just a few more points drawn from other authorities.
15. Carr LJ's summary of the scope of the "factual matrix" represents the distillation of a more general principle contained in a frequently cited passage of Lord Hoffmann's speech in *ICS v West Bromwich BS* [1998] 1 WLR 896 (HL) in which he explained that the factual matrix includes all "the background knowledge which would reasonably have been available to the parties and the situation in which they were at the time of the contract". In an internet age in which a large quantity of information is readily available to almost everyone, that has the potential to be a considerable amount of factual information indeed. At [279] of his judgment in *Challinor and others v Bellis and Egan* [2013] EWHC 347 (Ch) Hildyard J set out the following approach to refining the information assumed to be available to the parties and, since it was not suggested that I should apply any different formulation, I gratefully adopt it:

*(1) At least where there is no direct evidence as to what the parties knew and did not know, and as a corollary of the objective approach to the interpretation of contracts, the question is what knowledge a reasonable observer would have expected and believed both contracting parties to have had, and each to have assumed the other to have had, at the time of their contract: see per Vos J in *Spencer v Secretary of State for Defence* [2012] EWHC 120 (Ch) at paragraphs 65 to 74;*

(2) that includes specialist or unusual knowledge which only parties entering into a contractual engagement of the sort in question might reasonably be assumed to have; and it also includes knowledge which it is to be inferred, from the nature of the actions they have in fact undertaken, that they had or must have had;

(3) however, it does not include information that a reasonable observer would think that the parties merely might have known: that would open the gate too far to subjective or idiosyncratic speculation;

(4) the fact that material is readily available or notorious may support an inference as to what the parties actually knew;

(5) but (subject to (6) below) where it is demonstrated that one or more of the parties did not in fact have knowledge of the matter in question such knowledge is not to be imputed; nor is the test what reasonable diligence would or might have revealed: in either case, that would be inappropriately to introduce impermissible concepts of constructive notice or a duty (actionable or otherwise) to make inquiries or investigations: and see per Mann J in *Toth v Emirates and Another* [2012] EWHC 517 (Ch) at paragraph 44, agreeing with the analysis in the decision of MacFarlan J in the Supreme Court of New South Wales in *The Movie Network Channel case* [2010] NSWCA 111 (at paragraph 97);

(6) the exception is that a reasonable person cannot be assumed to be in ignorance of clear and well known legal principles affecting or incidental to the contractual engagement in question: see per Vos J in *Spencer v Secretary of State* at paragraph 72.

16. Next, as Lord Clarke noted in *Rainy Sky*, and as confirmed in *Wood v Capita*, interpretation of a contract is a “unitary exercise”. Where there are rival meanings, the court can give weight to the implications of those rival constructions by reaching a view as to which construction is more consistent with business common sense. The “unitary exercise” involves an iterative process by which each suggested interpretation is checked against the provisions of the contract and its commercial consequences are investigated. Where it is suggested that certain conclusions on the interpretation of the contract can be drawn from factual background, it does not matter greatly whether a court commences with a close examination of the relevant language of the contract, so long as the court balances the indications given by each. (See [10] and [12] of the judgment of the Supreme Court in *Wood v Capita*).
17. Also in *Wood v Capita*, the Supreme Court had this to say about the process of balancing competing indications provided by the text of a written contract and factual background:

13. Textualism and contextualism are not conflicting paradigms in a battle for exclusive occupation of the field of contractual interpretation. Rather, the lawyer and the judge, when interpreting any contract, can use them as tools to ascertain the objective meaning of the language which the parties have chosen to express their agreement. The extent to which each tool will assist the court in its task will vary according to the circumstances of the particular agreement or agreements. Some agreements may be successfully interpreted principally by textual analysis, for example because of their sophistication and complexity and because they have been negotiated and prepared with the assistance of skilled professionals. The correct interpretation of other contracts may be achieved by a greater emphasis on the factual matrix, for example because of their informality, brevity or the absence of skilled professional assistance. But negotiators of complex formal contracts may often not achieve a logical and coherent text because of, for example, the conflicting aims of the parties, failures of communication, differing drafting

practices, or deadlines which require the parties to compromise in order to reach agreement. There may often therefore be provisions in a detailed professionally drawn contract which lack clarity and the lawyer or judge in interpreting such provisions may be particularly helped by considering the factual matrix and the purpose of similar provisions in contracts of the same type. The iterative process, of which Lord Mance spoke in Sigma Finance Corpn (above), assists the lawyer or judge to ascertain the objective meaning of disputed provisions.

18. Therefore, there is no general rule that determines the precise amount of weight to be given to factual and commercial context, on the one hand, and indications from the words of a written contract on the other. As the Supreme Court notes in the above passage, that issue will depend on the precise circumstances of the particular agreement. However, as Leggatt LJ (as he then was) noted in *Minera Las Bambas SA v Glencore Queensland Ltd* [2019] EWCA Civ 972:

As a general rule, it may be appropriate to place more emphasis on textual analysis when interpreting a detailed and professionally drafted contract such as we are concerned with in this case, and to pay more regard to context where the contract is brief, informal and drafted without skilled professional assistance. But even in the case of a detailed and professionally drafted contract, the parties may not for a variety of reasons achieve a clear and coherent text and considerations of context and commercial common sense may assume more importance

The “exclusionary rule” relating to pre-contractual negotiations

19. The parties agree that there is an “exclusionary rule” that operates as a matter of common law, to restrict the admissibility evidence of what was said or done during pre-contractual negotiations. In *Chartbrook Ltd v Persimmon Homes Ltd* [2009] UKHL 38, the House of Lords declined to revisit the rule. After explaining the justification for retaining it, Lord Hoffmann said, at [42] of his judgment:

42 The rule excludes evidence of what was said or done during the course of negotiating the agreement for the purpose of drawing inferences about what the contract meant. It does not exclude the use of such evidence for other purposes: for example, to establish that a fact which may be relevant as background was known to the parties, or to support a claim for rectification or estoppel. These are not exceptions to the rule. They operate outside it.

20. I will consider the scope of the exclusionary rule in more detail in paragraphs 70 and 71 below when determining the admissibility or otherwise of emails on which Tesaro seeks to rely. For the time being I simply highlight that Lord Hoffmann’s formulation focuses not just on the time at which something was said or done but also the purpose for which the evidence is to be relied upon.

FINDINGS OF FACT

Overview and introduction

PARP inhibitors and their use in cancer treatment

21. Human cells rely on several types of DNA repair mechanisms, including base excision repair (“BER”) and homologous recombination (“HR”).
22. PARP inhibitors are substances that block the action of the poly ADP-ribose polymerase enzyme (“PARP”). PARP proteins are involved in BER which helps to repair damaged DNA in cells (both in normal and cancer cells) during cell division. Inhibiting PARP can therefore impair a cell's ability to repair DNA single-strand breaks, resulting in an accumulation of single-strand breaks which can give rise to DNA double-strand breaks at DNA replication forks.
23. PARP inhibitors can therefore damage or destroy dividing cells. That property means that they can be used to treat cancer. A detailed survey of the prior art before the grant of the Licensed Patents (which had priority dates in 2003) is not necessary in order to resolve the present dispute. However, in very broad summary prior to 2003 it was known that PARP inhibitors could be used to treat cancer in conjunction with other DNA-damaging treatments such as radiotherapy and chemotherapy.
24. The claims in the Licensed Patents are based on the discovery that PARP inhibitors could be used on their own as a treatment for cancers by targeting the HR pathway. The HR pathway is a type of DNA repair mechanism used by cells to repair DNA double-strand breaks. If a cancer cell is deficient in the HR pathway in some respect (i.e. if it is “HR deficient” or “HRD”), there is a prospect that the DNA double-strand breaks arising as a consequence of the application of a PARP inhibitor will go unrepaired and the cancerous cell will eventually die.

The Licensed Patents in outline

25. The treatments disclosed in the Licensed Patents apply the concept of “synthetic lethality”, namely that a cancerous cell might be able to survive defects in one type of DNA repair mechanism, but not two. More specifically, the second medical use to which the Licensed Patents is directed is the use of a PARP inhibitor in the treatment of cancer cells identified as HRD, the aim of such treatment being for the PARP inhibitor to induce double-strand breaks in cancerous cells which, because they are HRD, are not repaired by the HR mechanism.
26. The Licensed Patents are “second medical use patents”. They protect the new use of a wide set of PARP inhibitors in certain treatment regimes. Being second medical use patents, the Licensed Patents do not confer protection in respect of the PARP inhibitors themselves but just the use of PARP inhibitors in particular treatment regimes.

The Licence Agreements

27. Both AZ and Tesaro are engaged in, among other activities, research and development of products for the treatment of cancer.
28. In 2004, ICR and the University of Sheffield (as licensors) entered into exclusive licences of the Licensed Patents (the “Head Licence Agreements”) with a company called KuDOS Pharmaceuticals Limited (“KuDOS”). AZ acquired KuDOS in 2005 and following that acquisition succeeded to KuDOS’s rights and obligations under the Head Licence Agreements. As a result of that succession, AZ became entitled to grant sub-licences of the Licensed Patents.
29. Tesaro was incorporated in 2010. It saw potential in niraparib, a PARP inhibitor which was the subject of a patent held by Merck Sharp and Dohme Corporation (“Merck”). It obtained a licence from Merck to use the niraparib product. However, that licence could not give it the right to use niraparib as part of treatment regimes claimed in the Licensed Patents. It therefore sought, and obtained, the licences from AZ that are set out in the Licence Agreements. The Licence Agreements also extended to a product called “Mk-2512”. However, in the interests of brevity I will refer to both products together as “niraparib”.
30. Tesaro was correct to see the potential of niraparib. In 2017, it obtained authorisation from the US Food and Drug Administration (the “FDA”) for niraparib which it markets under the brand name Zejula. Zejula has also been authorised by the European Medicines Agency (“EMA”) since 2017.
31. It is common ground that the Licence Agreements oblige Tesaro to pay AZ royalties in respect of sales of Zejula. The dispute relates to the amount of royalties payable.

The circumstances in which Tesaro entered into the Licence Agreements

32. In 2012, both Tesaro and AZ would have known that a PARP inhibitor such as niraparib had the potential to be used as a monotherapy for the treatment of HRD cancers because of the concept of “synthetic lethality” that I have described above.
33. Moreover, Tesaro and AZ would have known that the BRCA1 and BRCA2 proteins are key components in the HR DNA repair pathway and that a loss of function of these proteins is a common cause of HRD. It follows that both Tesaro and AZ would have known in 2012 that identifying abnormalities in BRCA1 and BRCA2 proteins was a possible predictor of HRD. Accordingly, PARP inhibitors such as niraparib could be expected to have particular effect as a monotherapy in patients with BRCA1 and BRCA2 abnormalities, not because PARP inhibitors targeted the BRCA1 or BRCA2 proteins, but rather because abnormalities in those proteins were a possible indicator of HRD.
34. From Mr Moulder’s evidence I have concluded that in 2012 Tesaro was hoping to use niraparib as a treatment for i) patients identified as having BRCA1 or BRCA2 abnormalities who were therefore likely to be HRD; ii) patients in whom no BRCA1 or BRCA2 abnormalities had been detected but who were likely to be

- HRD nonetheless and iii) even more broadly in patients who had not been identified as HRD. I make no finding as to the extent to which Tesaro told AZ of its ambitions.
35. Use (i) set out in paragraph 34 was, as Tesaro would have recognised, likely to be within the scope of the claims in the Licensed Patents. Tesaro would have recognised that whether use (ii) had the potential to infringe the Licensed Patents was not entirely clear. Tesaro's belief at the time was that use (ii) would infringe only if the patient had been identified, by testing, as having an HRD cancer, but that begged the question of what "testing" had to be involved. Tesaro would have realised that some aspects of its contemplated use (iii), which included using niraparib in conjunction with chemotherapy, fell outside the claims of the Licensed Patents.
 36. Tesaro briefly considered whether it should challenge the validity of the Licensed Patents. However, it decided not to for a combination of reasons. In 2012 it was a relatively new company. It was about to embark on a significant fund-raising exercise to provide it with the funds necessary to conduct expensive trials associated with its plans for niraparib. It concluded that if it was involved in litigation on the validity of the Licensed Patents, that might reduce its attractiveness as an investment. It also reasoned that the likely royalty payable for a licence of the Licensed Patents would not be prohibitive. Tesaro also considered that the University of Sheffield and ICR made important contributions to cancer research so that it was appropriate for them to obtain reward for that. Tesaro therefore decided not to challenge the validity of the Licensed Patents but to seek licences to use them instead.
 37. At the time of the Licence Agreements, niraparib was not proven. It had shown promising results in a Phase 1 clinical trial in advanced cancer patients, but Tesaro still had a long, expensive and uncertain process ahead of it before it could be known whether niraparib could be developed profitably as hoped. As matters turned out, niraparib has proved to be effective, as demonstrated by the subsequent approval by the FDA and the EMA. However, that was by no means guaranteed in 2012.
 38. Since Tesaro did not know precisely how, if at all, it would be seeking to use niraparib, it needed a broad licence that gave it "freedom to operate" by developing and marketing niraparib as it saw fit. It did not need a licence that covered the use of all PARP inhibitors since its focus was on a small set of PARP inhibitors: niraparib and Mk-2512.
 39. Tesaro instructed a firm of English lawyers (Hogan Lovells) to act for it in the negotiation of the Licence Agreements. It also instructed a firm of US patent lawyers (Choate Hall & Stewart LLP) to provide it with US patent law advice. AZ used its in-house lawyers to negotiate the legal terms of the Licence Agreements.
 40. Before it signed the Licence Agreements, Tesaro was provided with copies of the Head Licence Agreements with the details of the royalty payable to ICR and the University of Sheffield redacted. Later in this judgment, I will consider the

significance or otherwise of the Head Licence Agreements as a guide to the proper construction of the Licence Agreements.

41. Also during the course of negotiations, in May and June 2012, Dr Emma Barton of AZ sent emails to Mr Adam Cooke of Hogan Lovells stating that AZ had “kept the costs so that they just cover AZ’s obligations to [ICR and the University of Sheffield]” with the result that AZ had “no room for manoeuvre”. The significance or otherwise of these emails as a guide to the proper interpretation of the Licence Agreements is disputed and will be considered later in this judgment.

Scope of Licensed Patents

42. As part of its case, Tesaro argues that the court should make factual findings relating to the scope of the claims under the Licensed Patents and the parties’ awareness thereof. AZ does not agree that factual findings on these issues will assist greatly in the interpretation of the Licence Agreements but does not go as far as to say that the matters raised are totally irrelevant.
43. Issues 1.1 to 1.4 on the parties’ agreed list of issues were as follows:
- i) Issue 1.1: Do the Licensed Patents claim the use of a PARP inhibitor in a method of treatment of cancer cells that are identified (by testing) as HRD cancer cells?
 - ii) Issue 1.2: Are HRD cancer cells, according to the Licensed Patents, notably found in individuals who have the BRCA1 or BRCA2 gene mutation?
 - iii) Issue 1.3: Do the relevant patent rights require a licence for the use of a PARP inhibitor in the treatment of cancer, otherwise than in a method of treatment which involves the prior identification of HRD cancer cells?
 - iv) Issue 1.4: Which, if any, of the facts and matters identified in Issues 1.1 to 1.3 were known or reasonably available to the parties at the date of the Licence Agreements?
44. By the time of the hearing, Issue 1.2 was common ground. The parties were agreed that abnormalities in the BRCA1 and BRCA2 proteins are indicators of HRD status but are not determinative of that status. A cancer in a patient who has BRCA1 and BRCA2 abnormalities is more likely to be HRD. However, that is not guaranteed. BRCA1 and BRCA2 abnormalities can be present, but the cancer can be non-HRD. Equally, patients without BRCA1 and BRCA2 abnormalities can have HRD cancers.
45. By the time of closing submissions at least, I did not understand Issue 1.4 to be in dispute. AZ had a different perspective from Tesaro on Issues 1.1 and 1.3. However, it did not suggest that any of the matters to be dealt with as Issues 1.1 and 1.3 were outside its knowledge or were not reasonably available to it in 2012. Since AZ chose to put forward no witness of fact who could speak to its knowledge or means of knowledge of matters falling within Issues 1.1 or 1.3, I will proceed on the basis that AZ accepts that the answer to Issue 1.4 is “all of them”.

The nature of the expert evidence before me

46. In the remainder of this section I will make factual findings on the Issues 1.1 and 1.3 which I take together. However, before doing so I make some observations on the evidence and process by which I am asked to make those findings.
47. First, AZ does not think the findings are necessary. Its position is that even if I make all the factual findings on those issues that Tesaro seeks, AZ's claim would still succeed. That meant that AZ did not engage in a full-blooded dispute on these facts although it did make clear that it did not agree with some of Tesaro's assertions.
48. Second, and related, although the matters raised in paragraph 43 ostensibly go to the scope of the disclosure and claims in the Licensed Patents, I am not asked to make findings as to the actual scope of those patents as at their priority dates in 2003 of the kind that would be necessary in infringement or invalidity proceedings. Tesaro relied on the expert evidence of Dr Krell, an oncologist, as to how an oncologist might have read the Licensed Patents in 2012 at the time Tesaro entered into the Licence Agreements. For its part, AZ relied on the expert evidence of Mr Hoxie, a lawyer, on the scope of the claims as at 2012.
49. Mr Hoxie and Dr Krell have very different areas of expertise. Therefore, the usual dynamic in which the experts are debating a point within their common area of expertise was somewhat missing in this case. Mr Hoxie was not equipped to debate points of oncology with Dr Krell and Dr Krell was not equipped to debate points of law with Mr Hoxie. Therefore, the expert evidence that I had consisted, on the one hand, of how an oncologist might interpret the claims in the Licensed Patents in 2012 and, on the other, how an appropriately qualified lawyer might interpret them.
50. Matters are complicated by the fact that Mr Hoxie made it clear that he was giving his opinions "in the hypothetical context that I was an attorney working for or advising a company considering freedom-to-operate for a PARP inhibitor in development as of October 2012". Since he was approaching the question from that perspective, his evidence contained some commentary on how such an attorney would approach a "freedom-to-operate" review. In agreement with Tesaro, I have concluded that this aspect of Mr Hoxie's evidence fell outside the terms of AZ's permission to rely on expert evidence.
51. The order permitting the parties to rely on expert evidence was made by Deputy Master Arkush on 26 May 2022. By paragraph 7 of the order, both parties were permitted to call up to two expert witnesses. Paragraph 8 of the order stipulated that the experts had to be experts in "the disclosure and scope of the claims of the Licensed Patents as at 4 October 2012" or in the US law doctrine of patent misuse.
52. AZ argues that all that was specified was the area of expertise and that, accordingly, Mr Hoxie who undoubtedly had the expertise specified was not limited to providing opinion evidence on the disclosure and scope of the claims of the Licensed Patents. It supports that submission by arguing that all along it had expressed doubts as to the usefulness of expert evidence in this area since it

considered that the dispute should properly be resolved by an analysis of the words used in the Licence Agreements.

53. I am unable to accept the submission set out in paragraph 52, which I consider involves an unduly literal reading of Deputy Master Arkush's order. The purpose of specifying the experts' field of expertise was so that they could give opinion evidence in that area of expertise. Deputy Master Arkush's order was not a general licence for an expert with multiple areas of expertise to give opinion evidence on issues not identified in the order. That conclusion is only reinforced by the fact that Deputy Master Arkush had the parties' agreed issues set out in paragraph 43 before him. Read in context, his order must have been intended to permit expert evidence that had a bearing on those issues specifically. That AZ considered that the expert evidence was less important than Tesaro did is of little significance as there is no suggestion in the order that AZ's reservations entitled it to any greater latitude as to the scope of its experts' reports.
54. I have, therefore, disregarded those aspects of Mr Hoxie's report that go beyond the disclosure and scope of the claims of the Licensed Patents as at 4 October 2012.

Conclusions

55. Although there are differences in the precise forms of the various Licensed Patents, the teaching in the specification of those patents is broadly similar. Both Mr Hoxie and Dr Krell agree that the teaching in the Licensed Patents, and thus the distinction over the prior art, is that the Licensed Patents specify the use of PARP inhibitors in the treatment of cancers that are "identified" as likely to be HRD. Where they differ is as to the kind of "identification" that is required and whether that requires the use of a scientific "test". That difference was brought out most clearly in paragraph 32 of Mr Hoxie's expert report in which he listed what he considered to be seven ways of "identifying" a cancer as HRD. He then advanced the opinion that there was at the very least a risk that some of these methods of identification could be performed without administering any "test", for example by concluding from a patient's family history or treatment history or the nature of the cancer itself that there is a likelihood of the cancer being HRD.
56. Given the points that I have made in paragraphs 47 to 49, it is not practicable for me to reach a conclusion as to a single "right" way to interpret the specification on this issue. Mr Hoxie and Dr Krell clearly read the specifications differently in the light of their differing expertise. However, the cross-examination of both experts revealed that there was a good degree of agreement and I can, therefore, reach the following conclusions on the issue:
 - i) Both an oncologist and a lawyer reading the specification of the Licensed Patents in 2012 would conclude that the overwhelming majority of the teaching in those patents involved identifying cancers as likely to be HRD by the application of some medical or scientific procedure.
 - ii) Describing the medical or scientific procedure as a "test" would risk confusion insofar as it suggests a high degree of certainty. In 2012, there was no single laboratory test that could be performed that would determine

conclusively whether a cancer is, or is not, HRD. Therefore, the procedure involved would seek to ascertain whether there were indications of likely HRD status in response to that medical or scientific procedure.

- iii) The medical or scientific procedure could certainly involve something described as a “test”. For example, a genetic test on a sample from a cancer might indicate whether there are variations such as polymorphisms or mutations in a nucleic acid encoding a polypeptide which is a component of the HR dependent DNA double-strand break repair pathway. If such variations are present, that would indicate a likelihood of the cancer being HRD.
- iv) However, the medical or scientific procedure need not involve a “test” in the sense of taking a sample and subjecting that sample to analysis. The procedure might simply involve observing how the patient had responded to other treatments. In 2012, it was considered that HRD cancers were particularly sensitive to treatments involving platinum. Therefore, a good response to platinum treatment, with the possible indication of HRD that came with it, was an example of the medical or scientific procedure involving “identification” of HRD that was set out in the specification of the Licensed Patents.
- v) An oncologist reading the Licensed Patents in 2012 would conclude that “identification” of a cancer as HRD would, in all cases, involve a medical or scientific procedure of the kind described above.
- vi) However, a patent attorney would see room for doubt on that issue. A patent attorney would conclude that it is reasonably arguable that inferring likelihood of HRD from a patient’s family history would also constitute “identification” covered by the specification of the Licensed Patents. The kind of “family history” a patent attorney might have in mind is the situation where, for example, a patient has ovarian cancer and both her mother and her grandmother on her father’s side also had ovarian cancer.
- vii) An oncologist in 2012 would not regard the process of inferring likely HRD status from a cancer patient’s family history as particularly reliable.
- viii) Tesaro’s belief in 2012 that some of the uses of niraparib that it was considering would involve no infringement of the Licensed Patents was therefore appropriately grounded in the wording of those patents as they would be read by an oncologist.

Reasons for these conclusions

- 57. The conclusions that I have set out in paragraph 56 above represent a distillation of relevant points that emerged from the cross-examination of Dr Krell and Mr Hoxie.
- 58. In particular, Mr Hoxie was taken in detail through the specification of one of the Licensed Patents namely US 8,071,579 (“US 579”). While AZ had at points submitted that Dr Krell had been “selective” in the patents that he analysed, there

was no real attempt to suggest that the specification of US 579 was materially different from those of the other Licensed Patents. I therefore take the answers that Mr Hoxie gave in cross-examination relating to US 579 as representative of his opinion on the Licensed Patents generally.

59. During that cross-examination, with the exception of the two points below, Mr Hoxie came to accept that even if some of the methods of “identification” that he had set out in paragraph 32 of his report might not involve a “test” as that word is often understood, they did involve the application of some medical or scientific procedure.
60. Mr Hoxie did not accept that any medical or scientific procedure was involved in relation to an extract found at column 14, lines 53 to 56 of US 579. However, I have concluded that he was misreading that extract which was indicating a possible method of treatment of a cancer rather than a method of identifying whether it was HRD.
61. That just left Mr Hoxie’s point on “family history”. He did not suggest that his interpretation of the specification on this point was much the better interpretation. Rather, consistent with the fact that he was approaching his evidence from the standpoint of an attorney considering freedom-to-operate issues, he described it as a “risk”. It is for that reason I conclude only that a patent attorney would regard the proposition based on family history as “reasonably arguable”.
62. In his Reply Expert Report, Dr Krell expressed the professional opinion that using a cancer patient’s family history as a possible indicator of the cancer being HRD was not very reliable. That conclusion was not challenged or contradicted in AZ’s expert evidence, not least because AZ had no oncology expert of their own equipped to express a contrary view to that of Dr Krell.

The Head Licence Agreements

63. Issue 1.5 on the parties’ agreed list is:

Are the terms of the Head Licence Agreements relevant to the construction of the Licence Agreements? If they are, is the Claimant’s obligation to pay royalties under the Head Licence Agreements relevant and, if so, what was that obligation?

64. In my judgment, the terms of the Head Licence Agreements are “relevant” in the sense of being part of the factual matrix. AZ was aware of the terms of the Head Licence Agreements since it had succeeded to the rights and obligations of KuDOS under those agreements. Tesaro was provided, before it executed the Licence Agreements, with copies of the Head Licence Agreements redacted to remove details of the payments that AZ was obliged to make to ICR and the University of Sheffield and was therefore aware of the terms of the agreements so redacted.
65. Copies of the Head Licence Agreements with details of the royalties payable to ICR and Sheffield redacted were put into evidence. Tesaro argues that it is plain from a straightforward reading of those agreements that they require payment of a royalty only on sales of products (whether effected by AZ itself or by a sub-

licensee of AZ) that would infringe the Licensed Patents (i.e. that the Head Licence Agreements provided for a royalty to be payable on a “pay to infringe” basis). AZ made few submissions as to the scope of the royalty obligations in the Head Licence Agreements. It argues that the Head Licence Agreements had nothing to say about the scope of the royalty obligation in the Licence Agreements.

66. I do not accept Tesaro’s argument that it is clear that the Head Licence Agreements were entered into on a “pay to infringe” basis. Clauses 5.4 and 5.6 of the Head Licence Agreement with ICR suggest that AZ’s obligation when, as here, it had granted sub-licences, was to pay over a percentage of royalties received from the sub-licensee. That formulation of the obligation did not explicitly address any distinction between infringing and non-infringing use. The Head Licence Agreement with the University of Sheffield was somewhat different. Clause 6.4 of that agreement required AZ to pay a royalty calculated as a percentage of “Net Sales”. The definition of “Net Sales” included sales by sub-licensees. Once the architecture of the various definitions in the agreement is considered, it is certainly possible to make a good case that only Net Sales that would infringe the University of Sheffield’s Licensed Patents trigger a royalty payment. However, I do not regard the position under either Head Licence Agreement as “clear” in the way that Tesaro suggests. The separate question whether the parties proceeded on the basis of a common belief that the Head Licence Agreements carried a “pay to infringe” royalty is considered in the next section dealing with Issue 1.6.
67. While I conclude that the Head Licence Agreements are relevant as being part of factual matrix, I do not consider that the Head Licence Agreements and the Licence Agreements form part of the “same transaction” so as to engage the principle set out in paragraphs 3.06 and 3.07 of *Lewison – The Interpretation of Contracts* 7th Edition (2020) with the result that they are read together for the purpose of determining their legal effect. The two sets of agreements were executed several years apart and involved different contracting parties.

Whether AZ had a policy of not making a profit out of royalties charged under the Licence Agreements

68. Issue 1.6 on the parties’ agreed list is whether there was a common understanding between the parties at the date of the Licence Agreements that AZ had a policy not to make a profit on the royalty charged to sublicensees but merely to cover the costs of the royalties payable under the Head Licence Agreements.
69. That issue has its roots in two emails that Dr Emma Barton of AZ sent to Adam Cooke of Hogan Lovells, the English solicitors acting for Tesaro, on 23 May 2012 and 2 June 2012. The email of 23 May 2012 dealt with the Licence Agreement relating to patents licensed from ICR. The email of 2 June 2012 made similar points in relation to patents licensed from the University of Sheffield. The emails were in materially identical terms and so I focus on the email of 23 May 2012. In that email, Dr Barton set out the broad terms of what she described as a “non-binding offer” that dealt only with financial aspects of the proposed Licence Agreement. She set out an overview of the proposed financial terms of the Licence Agreement and then wrote:

The financials have been set [so] AZ can cover its financial obligations to the ICR, we don't seek to make a profit on this and therefore have no room for manoeuvre. I would be happy to talk you through this if you would like? If your clients are happy with the financials I would be happy to provide a draft contract for their review if you could provide me with their detail.

70. I agree with Tesaro that this email is admissible evidence, at least given the way in which Tesaro wishes to rely on it. Tesaro does not say that this email demonstrated that the parties had achieved consensus at this early stage of the negotiations that the Licence Agreement would contain a pay to infringe royalty. Rather, it relies on the email only as “factual matrix” and as indicating that the parties were both aware that they were contracting against the backdrop of a “policy” to the effect that AZ would not be seeking to make a profit out of the Licence Agreement. That kind of reliance, in my judgment, involves seeking “to establish that a fact which may be relevant as background was known to the parties” with the result that the evidence is admissible in the light of the extract from Lord Hoffmann’s speech in *Charbrook Ltd v Persimmon Homes Ltd* set out in paragraph 19 above.
71. Lord Hoffmann said that evidence of what was said or done during the course of negotiations is not admissible “for the purpose of drawing inferences about what the contract meant”. Of course, ultimately the reason why Tesaro wishes to rely on the presence of the averred “policy” is to support its case on the proper interpretation of the agreements. However, if this rendered the evidence inadmissible, there would be nothing left of Lord Hoffmann’s statement that reliance for the purpose of establishing background known to the parties is permissible since ultimately the only reason why “factual matrix” evidence is introduced in the dispute about contractual interpretation is to advance one party’s case on the correct interpretation.
72. However, having treated the evidence as admissible, I am quite unable to accept that it demonstrates that the parties were transacting on the basis of a common understanding as to AZ’s “policy”. The email sets out a negotiating position. Dr Barton indicates that AZ is unlikely to accept any requests for a reduction in royalties or other sums payable under the Licence Agreements because it is proposing to set those at a level that, it thought, would enable it to discharge its obligations to ICR and the University of Sheffield without making a profit. So the email signals that, if the “financials” propose a royalty of x%, AZ is unlikely to entertain a request for a royalty at the lower rate of y%. Nor can the email be read as articulating any “policy” to the effect that the royalty payable under the Licence Agreements would be calculated on the same basis as the royalty payable under the Head Licence Agreements. The email simply did not give sufficient detail on the royalty payable to articulate such a policy: all it said was that a “small royalty” would be payable. It did not indicate whether the royalty would be based on total sales or would be calculated on a pay to infringe basis. Nor did it give any detail as to the basis on which the royalty in the Head Licence Agreements was payable.
73. For similar reasons, applying the principles in *Challinor and others v Bellis and Egan*, I do not consider that a common belief that the Head Licence Agreements required a “pay to infringe” royalty formed part of the factual matrix. As I have

explained, it is by no means clear that those agreements do require a “pay to infringe” royalty. While I accept Mr Moulder’s evidence that he wanted to review the Head Licence Agreements to confirm that the sub-licences Tesaro was being offered were “in line with the obligations in [AZ’s] licences”, I do not consider that Dr Barton’s emails would have prompted Tesaro to conclude positively that the Head Licence Agreements were on a “pay to infringe” basis. Nor do I consider that a reasonable observer would conclude that Tesaro would be transacting on the basis of such a belief.

Patent misuse

74. The parties agree that in principle the US federal law concept of “patent misuse” is of some relevance to the construction of the Licence Agreements. That is because the Licensed Patents include US patents and the US was a major market for both AZ and Tesaro. Moreover, if the Licence Agreements did contain terms that fell foul of the doctrine of patent misuse then the consequences were potentially adverse for both parties. Tesaro relies on the concept of “patent misuse” in the following respects:
- i) First, it argues that, there was at the least a significant risk that the total sales royalty which AZ argues is payable under the Licence Agreements would fall foul of the doctrine of patent misuse once that doctrine is properly understood.
 - ii) Second, it argues that in light of those consequences, the court should not impute to the parties an intention to agree a total sales royalty.
75. The scope of the doctrine of “patent misuse” raised by the issue summarised in paragraph 74.i) is a matter of US federal law. It is, therefore, a question of fact for this court to determine. In the section that follows I will set out my conclusions on that factual question. The second issue, raised in paragraph 74.ii) is an aspect of the English law question of construction which I will deal with in paragraphs 145 to 151 below.

Factual conclusions

76. I was greatly assisted by the expert witnesses for the parties (Mr Belvis for AZ and Judge O’Malley for Tesaro) on the scope of the doctrine of patent misuse. I do not accept Tesaro’s submission that Mr Belvis’s expert opinion was vitiated by an unspoken assumption that it was Tesaro who proposed a total sales royalty to AZ. Mr Belvis was not giving an opinion limited to the circumstances of this transaction. He was giving an opinion on the patent misuse doctrine generally. However, I do agree, for reasons that are similar to those I have given in relation to Mr Hoxie’s expert report, that parts of Mr Belvis’s report strayed beyond issues on which expert evidence was permitted. I have, therefore, disregarded Mr Belvis’s opinion evidence on how a patent licensing professional would proceed when negotiating patent licenses and what knowledge of US and other law such a professional would have. I will, however, have regard to Mr Belvis’s opinions on aspects of the correspondence between AZ and Tesaro in the course of negotiations not, of course, as a guide to the meaning of the Licence Agreements under English law but rather as a guide to the scope of the patent misuse doctrine.

An explanation of how the doctrine is thought to apply in particular cases can shed some light on the nature of the doctrine generally.

77. In this section, I will set out my overall conclusions on relevant aspects of the doctrine as a matter of US law. In the subsequent section, I will set out fuller details of my reasoning, focusing on those areas on which Mr Belvis and Judge O'Malley did not agree.
78. The doctrine of patent misuse is an equitable doctrine largely developed by the US federal courts with some restrictions placed upon it by Congress by statute. By way of broad overview, the doctrine is an affirmative defence whose purpose is to prevent harm to the market caused by a patentee seeking to extend the scope of a patent beyond that which the law allows.
79. The doctrine is an “affirmative defence” in the sense that it is a defence to a liability which a person might otherwise have to the patentee in connection with the patent. For example, it can be a defence to infringement proceedings. More relevantly in the context of these proceedings, it can be a defence to a contractual claim for a patent royalty. The doctrine is not an “affirmative claim” so, even if aspects of the Licence Agreements did fall foul of the doctrine, US law would not give Tesaro the right to claim damages against either AZ or the holders of the patents concerned.
80. The doctrine is capable of applying in the present context where the Licence Agreements were granted, not by the holders of the patents themselves, but rather by AZ in its capacity as licensee under the Head Licence Agreements. If aspects of the Licence Agreements that AZ granted to Tesaro fell foul of the doctrine, then the Licensed Patents would become unenforceable until the patent misuse in question had been “purged”. That would be an adverse consequence for ICR and the University of Sheffield, as holders of the Licensed Patents. It would also be an adverse consequence for AZ whose own rights under the Head Licence Agreements were predicated on the enforceability of the Licensed Patents.
81. The doctrine of patent misuse has largely been developed by the US federal courts. The scope of the doctrine has, over time, been restricted (or, using terminology found in US cases, it has been “cabined”) both by statute and by subsequent judgments of the US federal courts. By 2012, when the Licence Agreements were executed, it had “largely been confined to a handful of specific practices” (*Princo Corp. v. International Trade Comm*, 616 F.3d 1318, 1329 (Fed. Cir. 2010) (quoting *USM Corp. v. SPS Techs., Inc.*, 694 F.2d 505, 510 (7th Cir. 1982)). Those specific practices included, but were not necessarily limited to, the following:
 - i) “tying arrangements” under which a patentee requires a licensee to purchase separate non-patented items as a condition of obtaining a patent licence. The potential for such tying arrangements to give rise to patent misuse was constrained by statute in the form of the 1988 Patent Misuse Reform Act, but they remained in principle capable of constituting patent misuse;

- ii) “post-expiration royalties” under which a patentee requires a licensee to pay patent royalties on sales occurring after the patent expires; and
 - iii) “total sales royalties” under which royalties are calculated not only on sales of the product covered by the patent, but also on sales of products or components not covered by the patent.
82. At issue in these proceedings is the scope of the doctrine as applicable to total sales royalties of the kind summarised in paragraph 81.iii). I have reached the following conclusions on that issue with all those conclusions being based on the scope of the doctrine in 2012, when the Licence Agreements were executed.
- i) The inclusion in a patent licence agreement of a royalty based on total sales, and not just on sales of the patented product or process, is capable of amounting to patent misuse. Whether it does, or does not, amount to patent misuse will depend in many cases on an analysis of matters other than the wording of the contract, for example negotiations between the parties leading up to the total sales royalty and the way in which the patentee dealt with other licensees.
 - ii) There is patent misuse if a patent holder “conditions” the grant of a patent licence on the payment of royalties on products which do not use the teaching of the patent.
 - iii) “Conditioning” for these purposes is present where the patentee refuses to license on any other basis and leaves the licensee with a choice between a licence containing a total sales royalty and no licence at all. Thus, there is likely to be patent misuse if a licensee asks to pay a royalty based on use of the patented product or process, but the patentee refuses and offers only a total sales royalty.
 - iv) The test is whether there is “conditioning” in the sense set out above. That could legitimately involve an analysis of similar concepts such as whether the patentee is “coercing”, “bullying” or “strong-arming” the licensee into taking a total sales royalty. Whether a patentee has engaged in behaviour of that kind might well be relevant to a court’s evaluation as to whether “conditioning” is present. However, that is not to be elevated into a free-standing “test”. There can be “conditioning” without any overt aggressive or coercive behaviour by a patentee because the test is focused not on expressions that a patentee might use during the course of negotiations but on whether the patentee is using “leverage” that comes from the patent itself to derive a benefit not attributable to use of the patent’s teachings.
 - v) There will not be any “conditioning” if a total sales royalty is agreed for the mutual convenience of both patentee and licensee.
 - vi) However, point v) above does not mean that there is a binary choice between objectionable “conditioning” on the one hand and benign “mutual convenience” on the other. If the total sales royalty is driven entirely by the “convenience” of the patentee with the result that the patentee refuses a licensee’s request to pay a royalty based only on use of the patented product

or process there is likely to be patent misuse on the basis that there has been straightforward “conditioning” of the kind set out in paragraph iii). However, if a licensee requests a total sales royalty for the licensee’s own convenience, but the patentee is either ambivalent about the proposal or even regards it as “inconvenient”, there was no rule of law in 2012 that would have resulted in the total sales royalty necessarily constituting patent misuse.

- vii) In cases such as this, there may be a debate as to whether as a matter of construction, a particular licence agreement contains a total sales royalty or not. In such a case, a US court would obviously need to know the correct interpretation of the agreement before making a finding of patent misuse. However, there is no principle of law that would require a US court to start with an analysis of the contract. Nor is there any principle of law that would require a US court to start by analysing the conduct of the parties to see whether the requisite “conditioning” was present.
- viii) Where a licence agreement includes a total sales royalty and the parties agree an express contractual statement that it was agreed for their mutual convenience, the court will have regard to that statement. However while the inclusion of such a clause would be an indication of weight that there is no patent misuse, neither the presence nor absence of such a statement is dispositive. There could be patent misuse if a licence agreement contains such a statement. Equally, the absence of such a statement from a licence agreement does not demonstrate that a total sales royalty amounts to patent misuse.
- ix) If the Licence Agreements required Tesaro to pay a royalty based on total sales, there would be a risk that it would fall foul of the doctrine of patent misuse. It would not have been practicable for the parties, without taking detailed US patent law advice to quantify the extent of the risk. Eminent experts such as Judge O’Malley and Mr Belvis hold very different views on the scope of the patent misuse doctrine as at 2012. Therefore, if the parties had taken advice, they would probably have been told that the position was uncertain, with advisers subscribing to Mr Belvis’s view of the doctrine being more confident and advisers subscribing to Judge O’Malley’s view being less confident. If the parties had taken advice, they would have been told that the risk could be reduced, but not eliminated, by including a statement in the Licence Agreements that any total sales royalty was included for reasons of mutual convenience.

The conclusions in paragraphs 82.i) to 82.iv) - reasons

83. I did not understand my conclusions in paragraphs 82.i) to 82.iii) to be controversial. The principles that I have identified in those paragraphs come from what both Mr Belvis and Judge O’Malley agreed to be the two leading judgments of the US Supreme Court in the area. The first judgment was given in 1950 in *Automatic Radio Co. v. Hazeltine* 339 U.S. 827 (1950) (“*Automatic Radio*”). The later judgment was given in 1969 in *Zenith Corp. v. Hazeltine*, 395 U.S. 100 (1969) (“*Zenith*”).

84. In *Automatic Radio*, the patentee granted a licence agreement for a term of 10 years. Under that licence agreement, the licensee was granted the right to use any or all of the patents that the patentee held in the manufacture of radio broadcasting receivers. The royalty was based on a percentage of the selling price of complete radio broadcasting receivers subject to a minimum of \$10,000 per year.
85. Before the District Court, the licensee had suggested that the patentee refused to grant a licence under any one or more of its patents to anyone who refused to take a licence of all of its patents. However, that did not form the basis of its assertion of patent misuse before the Supreme Court. Rather, the licensee's argument before the Supreme Court was that it should not have to pay the minimum licence fee of \$10,000 because it had not used all of the patents for which it had been granted a licence in the manufacture of radios in the particular year. The Supreme Court rejected that argument holding that the licence agreement involved no inherent extension of the monopoly of the patent. The licensee had acquired the privilege of using any or all of the patents. It could not complain if as matters turned out it used none of them.
86. The *Zenith* case focused on the same patentee's insistence that licensees should take a standard five-year package licence agreement covering all its 500-odd patents and pay royalties based on total radio and television sales, irrespective of whether the licensed patents were actually used in the products manufactured. The court below granted an injunction restraining the patentee from "conditioning" the grant of the patent licence on either (i) the licensee taking a licence under any other patent or (ii) upon the paying of royalties on the manufacture, use or sale of apparatus not covered by such patent.
87. The Supreme Court in *Zenith* was concerned with the question whether the court below was right to grant injunction (ii) set out in paragraph 86 above. There was an obvious read-across to the *Automatic Radio* case because in *Automatic Radio*, the Supreme Court had found nothing objectionable in the total sales royalty at issue in that case.
88. The principles that I have set out in paragraphs 82.ii) and 82.iii) above are more or less direct quotes from the judgment of the Supreme Court in *Zenith*. *Automatic Radio* had determined that a total sales royalty was not objectionable patent misuse on its own. However, where the grant of the licence was "conditioned" on the total sales royalty the position was otherwise and the Supreme Court explained what it meant by "conditioning" in this context.
89. It was suggested to Mr Belvis in cross-examination by reference to the judgment of the US District Court in *Glen Manufacturing, Inc v Perfect Fit Industries, Inc* 324 F Supp 1133 (1971), that there would be "conditioning" if the patentee did not positively offer a licensee the ability to pay a royalty calculated only by reference to sales of the patented goods. However, I agree with Mr Belvis that, while this is a relevant consideration, it is not itself enough to demonstrate "conditioning". I acknowledge that in paragraph 12 of *Glen Manufacturing* the court noted that the licensee was given two options namely to pay a royalty based on total sales or to stop altogether the manufacture of allegedly infringing products. The court noted that the patentee did not offer the opportunity to pay a royalty based on manufacture of patented goods only and concluded "thus... it

conditioned granting of a licence upon acceptance of a royalty based on total sales”. However, the conclusion introduced by “thus” does not follow solely from the absence of an offer to accept a royalty based only on sales of patented goods. Viewed in context, the court’s conclusion was based on the fact that the patentee was offering the licensee a choice between a royalty based on total sales and no licence at all: precisely the kind of “conditioning” that the Supreme Court had explained to be objectionable in *Zenith*.

90. I did not consider the principle set out in paragraph 82.i) to be controversial. The Supreme Court in *Zenith* itself referred to the significance of the negotiations leading up to the grant of the licence. Indeed, as will be seen, one of the bases on which *Automatic Radio* was distinguished was because the court had not in that case been invited to consider those negotiations.
91. The principle that I have set out in paragraph 82.iv) was controversial. Mr Belvis in his oral evidence suggested on occasions that “conditioning” was synonymous with “strong-arming”, “coercion” or “bullying”. For her part, Judge O’Malley emphasised that the “conditioning” to which the Supreme Court referred was an aspect of inappropriate “leveraging” of the patent itself rather than simply being an aspect of the patentee’s conduct during negotiations. As Judge O’Malley said in her oral evidence “the leverage is not screaming and yelling and strong-arming, the leverage is the patent itself”. I preferred Judge O’Malley’s conclusion on this issue which found echo in the Supreme Court’s judgment in *Zenith*. Her conclusion also had the advantage of focusing on the precise words that the Supreme Court had used rather than on words, said to be synonymous, but which the Supreme Court had not used.

The conclusions in paragraphs 82.v) and 82.vi) – reasons

92. The conclusion that I have set out in paragraph 82.v) was not controversial and emerges from the judgment of the Supreme Court in *Zenith* itself.
93. The conclusion set out in paragraph 82.vi) was much more controversial. Both Mr Belvis and Judge O’Malley’s cross-examination explored a hypothetical situation in which a licensee asks a patentee for a licence bearing a total sales royalty to suit the licensee’s own convenience. They were asked whether there would be patent misuse if the patentee was agnostic about the proposal on the basis that it was neither convenient nor inconvenient for the patentee who was prepared just to go along with what the licensee had suggested. Mr Belvis’s opinion was that there could be no patent misuse in that situation. Judge O’Malley had a different opinion. She thought that there would be patent misuse on the basis that there was no “mutual” convenience of the parties and that accordingly, the patent itself was being unduly “leveraged”.
94. Part of the difficulty with this example was that it was both speculative and hypothetical. It is difficult to envisage a real-world scenario in which total sales royalty would be “convenient” for a licensee, but less convenient for a patentee. However, the parties clearly attached some significance to the issue as much of the cross-examination of Mr Belvis and of Judge O’Malley focused on it.

95. I prefer the opinion of Mr Belvis as being more consistent with the extracts from the authorities as they stood in 2012.
96. I start with the basis on which the Supreme Court in *Zenith* distinguished *Automatic Radio*. Judge O'Malley suggested that the Supreme Court regarded *Automatic Radio* as dealing with “circumstances where the parties collectively believed that the best way to structure royalty was one that would make most sense...”. However, as noted in *Zenith* itself, there was no analysis in *Automatic Radio*, of the parties’ negotiations. It follows, therefore, that the distinguishing feature in that case was not a positive finding that a total sales royalty was for the “mutual convenience” of both parties. The Supreme Court in *Automatic Radio* did comment that “sound business judgment could indicate that [a total sales royalty] represents the most convenient method of fixing the business value of the privileges granted by the licensing agreement”. However, the Supreme Court did not reference any finding that a total sales royalty was the most convenient method in the case before it. Moreover, the Supreme Court qualified its reference to “sound business judgment” by noting that “We are not unmindful that convenience cannot justify an extension of the monopoly of the patent”.
97. I prefer Mr Belvis’s explanation of the basis on which *Automatic Radio* was distinguished namely that, in *Automatic Radio*, the courts were not invited to find that there had been any “conditioning” of the grant of a licence on a total sales royalty and the courts had therefore not considered conclusions that should be drawn from the course of the parties’ negotiations. That is what the Supreme Court said at [138] of *Zenith*.
98. In that section, the Supreme Court went on to comment that:

It could easily be, as the Court indicated in Automatic Radio, that the licensee as well as the patentee would find it more convenient and efficient from several standpoints to base royalties on total sales than to face the burden of figuring royalties based on actual use. If convenience of the parties rather than patent power dictates the total-sales royalty provision, there are no misuse of the patents and no forbidden conditions attached to the license.

99. I agree with Mr Belvis’s opinion that, in this passage the Supreme Court is not setting up a binary distinction between the “mutual convenience of the parties” on the one hand and “conditioning” on the other. Rather, the Supreme Court is indicating that the convenience of (both) parties is one of potentially many factors that could point against the conclusion that a total sales royalty was “conditioned”. That the passage is not setting out a binary test is apparent from the introductory phrase “It could easily be...”.
100. Tesaro places emphasis on the fact that, in his dissent, Justice Harlan started his remarks by commenting:

... I do not join Part III, in which the Court holds that a patent license provision which measures royalties by a percentage of the licensee’s total sales is lawful if included for the “convenience” of both parties but unlawful if “insisted upon” by the patentee.

Viewed in isolation, his reference to the convenience of both parties supports the existence of the “binary choice” for which Tesaro argues. However, I accept Mr Belvis’s opinion that this passage is a high-level summary that serves as an introduction to Justice Harlan’s dissent rather than an attempt to summarise in its entirety the *ratio* of the majority’s decision. That conclusion is reinforced by an analysis of the dissent itself. Justice Harlan’s reservation is that any attempt to reach conclusions by reference to negotiations between the parties would lead to undesirable uncertainty. That reservation was just as valid if “mutual convenience” was simply an aspect of a wider enquiry as to the presence of “conditioning”.

101. Tesaro argues that the interpretation set out in paragraph 99 is inconsistent with the way in which other federal courts have applied *Zenith*. It notes that, in paragraphs [1] and [2] of the “Discussion” section in *Glen Manufacturing*, the US District Court said:

[1] Conditioning the grant of a patent license upon the payment of royalties based upon the manufacture of products which do not use the patent in their production constitutes a patent misuse...

[2] If the reason for employing a royalty provision which is based on is the mutual convenience of both of the parties rather than as leverage from which a licensor can extract payment for the manufacture of unpatented items, there is no patent misuse.

102. I accept Mr Belvis’s opinion that this passage simply concludes that “mutual convenience” prevents a finding of “conditioning”. If a total sales royalty is not positively convenient for the patentee, I quite accept that there will be no “mutual convenience”. However, the extract from *Glen Manufacturing* set out above does not compel the conclusion that the absence of “mutual convenience” means that there will necessarily be patent misuse.
103. More generally, I agreed with Mr Belvis’ opinion that other authorities on which Tesaro relies did not clearly articulate a binary choice between a total sales royalty satisfying the “mutual convenience of both parties” and objectionable patent misuse. This is not, as Tesaro submitted, to ignore completely questions of “mutual convenience”. The Supreme Court has made it clear that “mutual convenience” is a relevant consideration in the sense that, if present, it prevents a total sales royalty from giving rise to patent misuse. I give considerable weight to Judge O’Malley’s opinion, based on many years of public service on the bench, to the effect that there is a sound jurisprudential basis for setting out a binary choice of the kind she described. As she clearly explained, the underlying jurisprudential debate is between considerations based on freedom of contract (which would suggest that patentees and licensees should be allowed to contract on terms of their choosing) and considerations similar to those found in anti-trust law (which might point in favour of restricting the power of patentees who hold monopoly rights). I quite accept that the Supreme Court could choose to answer that debate in favour of restricting patentees’ rights concluding that there will be patent misuse unless a total sales royalty is for the convenience of both parties. However, having heard both experts’ opinions tested in cross-examination by reference to the reasoning of various decisions of US courts, I prefer the

conclusion that as at 2012 when the Licence Agreements were executed, the US federal courts had not articulated any such binary distinction.

The conclusion in paragraph 82.vii) – reasons

104. Mr Belvis and Judge O'Malley had different perspectives on this issue. Mr Belvis thought that a US court would start by considering whether there was a “quick answer” namely that the parties’ dealings made it clear that a total sales royalty was so freely negotiated as not to amount to patent misuse. Judge O'Malley thought that a court would start by construing the licence agreement in question on the basis that, if it did not provide for a total sales royalty, the question of patent misuse would not arise.
105. Both Mr Belvis and Judge O'Malley expressed their opinions in response to invitations in cross-examination to consider hypothetical questions. In those circumstances, it is not terribly surprising that their opinions differed. Neither expert’s opinion was clearly preferable to that of the other and neither demonstrated that their opinion was compelled by binding authority in the US. Given that two such eminent experts disagreed on the issue, I have concluded that there is no single “right” answer and that sometimes the circumstances of a case would suggest that a US court would start with the construction of the licence agreement and sometimes it would start with a consideration of the parties’ negotiations.

The conclusion in paragraph 82.viii) and 82.ix)– reasons

106. Ultimately, I did not consider there was significant disagreement between the experts on the issue raised in paragraph 82.viii). Both experts agreed that there were examples of the US federal courts giving real weight to express language in a contract to the effect that a total sales royalty was included for reasons of mutual convenience. The judgment of the Court of Appeals for the Federal Circuit in *Engel Industries, Inc v The Lockformer Company* 96 F.3d 1398 (Fed. Cir. 1996) is just one example. No example was put forward of a case in which a US court had found that there was patent misuse in cases where the parties had included such a “mutual convenience” clause in their contract.
107. I consider that the conclusion set out in paragraph 82.ix) follows naturally from my other conclusions on the scope of the patent misuse doctrine. I am fortified in the conclusion by the fact that in *Zenith*, in giving reasons for his dissenting judgment, Justice Harlan commented that one effect of the judgment of the majority is that in future district courts will have the unenviable task of deciding whether the course of negotiations established “insistence” on the suspect provision. Such determinations, he concluded, came with inherent uncertainty which would result in parties being unsure whether their agreements would be enforced.

THE QUESTION OF CONSTRUCTION

Terms of the Licence Agreements

108. There were two Licence Agreements: one referenced the patent licences granted in the Head Licence Agreement with the University of Sheffield and one referenced the patent licences granted in the Head Licence Agreement with ICR. The two agreements were, however, in materially identical terms and therefore in the remainder of this judgment I will simply refer to the “Licence Agreement” unless it is absolutely necessary to explain which particular document I am referring to.
109. Each Licence Agreement was governed by the law of England and Wales. As I have explained, both Licence Agreements were professionally drafted and executed after a process of negotiation between AZ and Tesaro.
110. Section 3.2 sets out the scope of the licence granted by each Licence Agreement as follows:

Subject to the terms and conditions of this Agreement, AstraZeneca hereby grants to TESARO and its Affiliates an exclusive (even as to AstraZeneca), royalty-bearing, license (the “License”) under AstraZeneca's rights in the Licensed Patents solely to Exploit the Compound and the Licensed Products within the Field in the Territory.

111. The royalty provisions are contained in section 5 of each agreement. Section 5.3 sets out the amount of royalty payable as follows:

5.3 Royalties. In partial consideration of the License and other rights granted by AstraZeneca to TESARO hereunder, TESARO shall pay to AstraZeneca during the royalty term stated in Section 5.5 a royalty of [a percentage was specified] of the aggregate Net Sales of Licensed Products in the Territory (provided that calculations for Combination Products shall be made in accordance with the formula set out in Section 5.4). TESARO shall have the responsibility to account for and report to AstraZeneca all sales of any Licensed Product that are subject to royalty payments under this Section 5.3.

112. Thus, it will be seen that the royalty payable under Section 5.3 was driven by the “aggregate Net Sales of Licensed Products in the Territory”. That phrase drew on the following terms that were defined elsewhere in Section 1 of the Licence Agreement:

- i) “Licensed Products” were (section 1.29):

the Product and the Combination Products

- ii) Neither party suggests that the definition of “Combination Product” has any bearing on this dispute. The “Product” was (section 1.46):

any product in a form suitable for human applications that contains the Compound as the sole active ingredient

- iii) The “Compound” was (section 1.11):

TESARO's PARP inhibitor compounds niraparib and Mk-2512 the use of which may be claimed or covered by, or the Exploitation of which may be claimed or covered by, one or more of the Licensed Patents

The emphasis in the above extract is my own. The wording that I have placed in bold typeface is a central plank of Tesaro’s argument that it had to pay a royalty on a “pay to infringe” basis only for what would otherwise be infringing use of niraparib.

- iv) The “Licensed Patents” were (section 1.28) those patents listed in Schedule 1, some of which had not yet been granted at the date the Licence Agreement was entered into.

- v) “Net Sales” were (section 1.34):

"Net Sales" means, subject to Section 5.6, for any period of determination, the gross amount invoiced for Licensed Products by TESARO, its Affiliates and their sublicensees to Third Parties during such period, less allowances for the following deductions, in each case as determined in accordance with, generally accepted accounting principles in the United States ("GAAP"): [a list of deductions followed]

- vi) The concept of to “Exploit” and “Exploitation” was defined in section 1.17 as:

"Exploit" means to make, have made, import, use, sell, or offer for sale, including to research, develop, register, modify, enhance, improve, Manufacture, have Manufactured, hold/keep (whether for disposal or otherwise), formulate, optimise, have used, export, transport, distribute, promote, market or have sold or otherwise dispose or offer to dispose of, a product or process and "Exploitation" means the act of Exploiting a product or process.

- vii) The “Territory” was (section 1.49) defined as being all countries in the world except for those countries in which the Licence Agreement had been terminated. Only the Licence Agreement relating to the University of Sheffield’s patents had a definition of “Field” which was “the use of the Compound for treatment of human diseases in oncology indications”. Neither party suggested that the definition of “Field” is of relevance or that it is significant that the definition was not used in the Licence Agreement relating to the ICR’s patents.

113. Sections 5.5 to 5.7 provided as follows:

5.5 Royalty Term.

5.5.1 *TESARO's obligation to pay royalties in respect of each Licensed Product shall commence, on a country-by-country basis, on the date of the First Commercial Sale of such Licensed Product in such country. In the event that in a particular country the First Commercial Sale of a Licensed Product occurs prior to the issuance in such country of a granted Patent which is a Licensed Patent that covers or claims the Exploitation of such Licensed Product, then royalties on such Licensed Product in such country shall be calculated pursuant to Section 5.3 and 5.4 from the date of the First Commercial Sale of the Licensed Product and the accumulated aggregate amount of such royalties shall be paid by TESARO to AstraZeneca within thirty (30) days of the issuance in the relevant country of such Licensed Patent.*

5.5.2 *TESARO's obligation to pay royalties shall expire, on a country-by country basis, with respect to each separate Licensed Product, at such time as there is no longer any Valid Claim that covers or claims the Exploitation of such Licensed Product in such country.*

5.6 Sales Subject to Royalties. *Royalties shall be calculated on TESARO's and its Affiliates' or their sub-licensees sale of the Licensed Products to a Third Party. For purposes of determining Net Sales, the Licensed Product shall be deemed to be sold when the sale is recognized in accordance with revenue recognition policies mandated by, as applicable to TESARO, GAAP or IFRS, consistently applied, and a "sale" shall not include, and no royalties shall be payable on, transfers of Licensed Products that are used as samples or in clinical trials or transfers or dispositions for charitable, promotional, preclinical, clinical, regulatory or governmental purposes.*

5.7 Royalty Payments. *The royalties shall be calculated quarterly as of the day of March, June, September and December respectively, for the Calendar Quarter ending on that date. TESARO shall pay royalties due in respect of each Calendar Quarter within sixty (60) days after the end of the Calendar Quarter. Such payment shall be accompanied by a written report to AstraZeneca that shows, with respect to each country, the sales volume, gross sales amount and Net Sales of each Licensed Product during such Calendar Quarter.*

114. Section 5.5 therefore had the following broad effects. First, it provided that royalties were payable on a country-by-country basis. Next, it provided that the obligation to pay a royalty on sales in a particular country commenced only when a patent was granted in that country that “covers or claims the Exploitation of the Licensed Product”. Finally, it provided for the obligation to pay a royalty in a particular country to cease once there is no longer a valid and enforceable patent that “covers or claims the Exploitation of the Licensed Product in such country”.

Inferences from terms

115. In this section of my judgment, I focus on inferences to be drawn from the language of the written contracts. In later sections I will consider the strength or otherwise of those inferences by reference to matters of “factual matrix”.
116. The way definitions are used in the Licence Agreement means that there is a degree of symmetry between the scope of the licence granted in section 3.2 and the royalty obligation in section 5.3. By section 3.2, Tesaro was given a licence (expressed to be “under” AZ’s own rights in respect of the Licensed Patents that were set out in the Head Licence Agreements) to exploit the “Compound” and the “Licensed Products”. Royalties in section 5.3 were to be calculated by reference to Net Sales of “Licensed Products”. The definition of “Licensed Products” itself drew on the definition of “Compound”. Therefore, broadening or narrowing the definition of “Compound” had the potential to affect both the scope of licence granted under section 3.2 and the amount of royalties payable under section 5.3. Moreover, Tesaro only needed a licence from AZ to the extent that its exploitation of niraparib would infringe the patents held by ICR and the University of Sheffield. AZ had no power to grant licences that permitted Tesaro to exploit niraparib in ways that might infringe any other patents (for example the patents in respect of niraparib itself held by Merck).
117. That definitional architecture suggests, at a high level, that royalties are to be paid on products that are sold by virtue of the patent licence and not on products that could be sold without a licence. However, there is a clear indication of a contrary intention when the definitions are considered in more detail. Only Net Sales of Licensed Products count towards the calculation of the royalty. When the definitions set out in paragraph 112 are put together, it can be seen that the question of whether a sale of a particular product is to count for royalty purposes is determined by asking whether that product “contains the Compound as the sole active ingredient”. Therefore, again at a high level of generality, this phrasing suggests that an analysis of whether one physical substance is present in another, rather than a consideration of the use to which products are put, is to drive the calculation of royalty.
118. That then leads to the definition of “Compound” which both parties agree to be at the heart of the dispute. If, as the title of the definition suggests, it references only a physical substance (niraparib or Mk-2512) there would be little to displace the indication set out in paragraph 117. However, the definition does not just refer to a physical substance but goes on to state:

the use of which may be claimed or covered by, or the Exploitation of which may be claimed or covered by, one or more of the Licensed Patents

119. Tesaro’s case relies strongly on these words as suggesting that the definition extends beyond an analysis of a physical substance and requires an examination of whether the use of that substance is “claimed or covered by” Licensed Patent. On that analysis, only uses that would otherwise infringe a Licensed Patent would be caught so that the royalty should be calculated on a “pay to infringe” basis.

120. However, that interpretation itself runs into two difficulties:
- i) First, the definition of “Compound” does not require that the use or Exploitation would be claimed or covered by a Licensed Patent, just that it “may be” so claimed or covered.
 - ii) Second, on any view the Licence Agreement provides for royalties to be payable by reference to sales. The parties have taken care in the Licence Agreement to specify what constitutes a Net Sale and when such a Net Sale is treated as taking place. However, particularly given the nature of the Licensed Patents, there are obvious difficulties with ascertaining whether a particular consignment of niraparib is to be used in a manner that would, absent the Licence Agreement, infringe the Licensed Patents or not. Tesaro could not know whether any particular box of niraparib is to be used to treat a patient, identified as having an HRD cancer (potentially infringing use) or whether it would be used as a combination therapy with a DNA-damaging agent, that formed part of the prior art and so would be non-infringing. If Tesaro’s interpretation is correct, some mechanism is needed to determine the question of “use”, but the Licence Agreement contains no such mechanism.
121. Tesaro’s first answer to the difficulty set out in paragraph 120.i) involves pointing out that some of the Licensed Patents were the subject of pending applications at the time of the Licence Agreement. Therefore, it argues that the words “may be” were words of futurity intended to deal with the future grant of those patents. I do not accept that interpretation. Even if some of the patent applications were pending, many of the Licensed Patents had been granted at the time of the Licence Agreement. If Tesaro’s analysis were correct, then it could be expected that the phraseology “is or may be” would be used so that both existing and future patents are covered. However, the definition uses only the phrase “may be” which in my judgment demonstrates that the Licence Agreement was not seeking by the use of the words “may be” to deal with future patents.
122. Tesaro’s second answer was stronger. It argues that the “may be” are words of futurity that related to the concepts of “use” and “Exploitation”, and simply reflected the fact that use or Exploitation would take place in the future. I agree that is a sustainable reading of the words. However, I do not consider it to be the most natural reading. All use and exploitation of niraparib by Tesaro necessarily had to take place after the Licence Agreement was entered into because Tesaro lacked the necessary rights until it entered into the Licence Agreement. No particular form of words was therefore needed to emphasise the fact that use and exploitation would take place in the future. The more natural reading of “may be” in my judgment is as referring to the extent of the use that is claimed by or covered by the Licensed Patents rather than the futurity of use or exploitation.
123. I consider the second objection, set out in paragraph 120.ii) to be of real force. As well as giving rise to the difficulties with calculation that I have highlighted, Tesaro’s interpretation would mean that ascertaining the amount of royalty payable would depend on a continuous review of the scope of claims under the Licensed Patents in 26 different countries. Tesaro counters that the Licence Agreement already requires some measure of country-by-country analysis

because of section 5.5.1 and section 5.5.2 of the Licence Agreement whose effect I have summarised in paragraph 114. However, sections 5.5.1 and 5.5.2 only require the scope of the Licensed Patents in any particular country to be analysed in order to determine two dates: the date on which royalties start to become payable in that country and the date when the obligation to pay royalties ceases. Tesaro's interpretation of the term "Compound" requires a continuous monitoring of the scope of each Licensed Patent in each country so that the royalty payable can be calculated. That is a more onerous requirement than is set out in section 5.5.

124. Tesaro seeks to downplay the significance of the calculation difficulties highlighted in paragraph 120.ii) by pointing out that "pay to infringe" licences are entirely common and that even Mr Hoxie accepted in a textbook that he co-authored that they are the norm. Moreover, Tesaro argues, the Head Licence Agreements were entered into on a "pay to infringe" basis and so the difficulties in ascertaining the royalty payable under its interpretation could be overcome.
125. I do not accept that an analysis of whether, as a matter of impression, pay to infringe licences can be described as "the norm" adds much to the question of interpretation of these specific Licence Agreements. Nor do I consider that interpretation of the Head Licence Agreements sheds much light on the matter. As I have noted, those agreements do not clearly require royalties to be calculated on a pay to infringe basis. Therefore, the difficulty or otherwise of calculating a "pay to infringe" royalty would be just as relevant to the interpretation of the Head Licence Agreements as it is to the interpretation of the Licence Agreement.
126. On the contrary, an analysis of the way in which Tesaro has approached the question of how to calculate royalties payable on its interpretation of the Licence Agreement demonstrates the difficulties and uncertainties to which its interpretation gives rise.
127. The Licence Agreements required Tesaro to provide periodic written reports to AZ showing, among other matters, Net Sales of Licensed Products. In its report for the fourth quarter of 2017, Tesaro took the position that this was to be calculated by reference to the "average prevalence of the BRCA1 and BRCA2 gene mutation worldwide". That approach caused it to conclude that a royalty was payable only in respect of 38% of sales. There is nothing in the Licence Agreement that supports that approach. As I have found, the Licensed Patents cover the use of a PARP inhibitor in a patient whose cancer has previously been identified as HRD. While BRCA1 and BRCA2 abnormalities are possible indicators of an HRD cancer, they are not synonymous with HRD status. Tesaro's own approach, therefore, was inconsistent with the interpretation of the term "Compound" that it now puts forward as being concerned with the actual scope of the claims in the Licensed Patents.
128. A further difficulty is demonstrated by the fact that Tesaro counterclaimed for a declaration that it was obliged to pay royalties based on the average prevalence of the identification of HRD cancer cells in patients treated with Zejula at 25% rather than 38%. Therefore, on Tesaro's interpretation of the Licence Agreement, the amount of royalty payable varies not just by reference to the scope of the claims of the Licensed Patents in 26 countries, but also by reference to

fluctuations in available statistical information on the average incidence of HRD cancer cells in patients treated with Zejula.

129. In making the points set out in paragraphs 127 and 128 above, I am not treating either party's performance, or purported performance, of the Licence Agreement as having a bearing on the interpretation of that agreement. Rather, I am highlighting what strike me as difficulties with the interpretation that Tesaro advances. It is no answer for Tesaro to say that many possible rational solutions to the difficulties are possible. A professionally drafted and negotiated contract did not seek to address these difficulties, suggesting that, viewed objectively, the parties did not consider they needed addressing. In my judgment, that is a strong pointer in favour of AZ's interpretation.
130. It is appropriate to test the strength of the inference set out in paragraph 129 against AZ's approach to the interpretation of the Licence Agreement. Tesaro argues that AZ's argument interprets the definition of "Compound" as if it referred only to a physical substance and therefore gives no effect to references to "use" in that definition. If that argument were correct, it would diminish the force of AZ's arguments against Tesaro's interpretation.
131. AZ's interpretation is that the definition of "Compound" references the use or Exploitation of the Licensed Patents that "may be claimed or covered" by the Licensed Patents rather than a reference to actual use following Net Sales effected by Tesaro. Tesaro's objection to that interpretation is that it is so uncertain as to be incapable of application since the degree of likelihood implicit in the words "may be" is not spelt out. There is some force in that objection, but it is not unanswerable.
132. I agree with Tesaro that the words "may be" are not referencing a pure measurement of probability since no minimum likelihood is stated as being necessary to satisfy the "may be" threshold. However, it is possible to read the words "may be" as referencing a different kind of possibility.
133. Both parties would have been aware that the Licensed Patents were all second medical use patents. AZ had no power to grant Tesaro a general licence to use or exploit niraparib. For example, to build on an argument that Mr Maclean KC made in his oral submissions, AZ could not grant Tesaro a licence to use niraparib as a treatment for hair loss. That was because the Licensed Patents only granted monopoly rights for certain uses of niraparib in treating cancer and AZ's own rights to grant licences came only from its head licence of the Licensed Patents. A definition of "Compound" that simply stopped after identifying niraparib and Mk-2512 would not have worked firstly because it might result in section 3.2 being read as conferring a licence on Tesaro to use niraparib as a treatment for hair loss (which AZ could not grant) and secondly because it might result in section 5.3 being read as obliging Tesaro to pay a royalty if it used niraparib as a hair loss product (which AZ did not seek).
134. In my judgment, it is this distinction, between licences that AZ had power to grant, and licences that it could not grant, that is being referenced by the addition of the words beginning "the use of which may be claimed or covered" in the definition of "Compound".

135. With hindsight, this drafting can be seen to have caused some confusion and difficulty. There may well have been better ways of bringing the point out other than simply adding extra words to the definition of “Compound”. However, the extract from the Supreme Court’s judgment in *Wood v Capita* demonstrates that even professionally drawn contracts can include provisions which lack clarity because of, for example, failures of communication, differing drafting practices or deadlines which require the parties to compromise in order to reach agreement. Therefore, even if the interpretation set out in paragraphs 133 and 134 is not perfect, or raises questions of its own, that is not fatal to the correctness of that interpretation.
136. I consider that AZ’s interpretation is much the better having regard to the words of the agreement. However, in light of the fact that neither rival interpretation based purely on the words of the Licence Agreement is without difficulty, as part of the “iterative process” referred to in the extract from *Wood v Capita* it is appropriate to test the rival interpretations in the light of the findings I have made on the factual matrix.

Inferences from the factual matrix

Inferences from the scope of the Licensed Patents (issues 1.1 to 1.4)

137. I have set out above my findings on Issues 1.1 to 1.4. In particular, I have found that both parties would have been aware that in 2012 there were uses of niraparib as a cancer treatment that did not fall within the scope of the claims in the Licensed Patents. The way in which Tesaro would actually use niraparib was not fixed in 2012 since niraparib still had to undergo further testing before it could be approved for use. However, I have concluded that Tesaro had in mind the possibility of using niraparib in ways that would not infringe the Licensed Patents. In cross-examination, Mr Hoxie memorably said that no one wanted to “be a chump and pay royalties for nothing”. Tesaro argues that it would be contrary to commercial common sense for it to be charged a royalty based on total sales of Zejula since that would make it the kind of “chump” that Mr Hoxie had in mind since such a formulation of the royalty would involve Tesaro paying for non-infringing use of Zejula.
138. I am unable to accept that argument. Precisely because its plans for Zejula were uncertain and the scope of the Licensed Patents was not certain, Tesaro sought and obtained a broad licence that would permit it to use niraparib in any of the multiple ways whose use might be claimed in the Licensed Patents. There was nothing commercially irrational in that course of action. It meant that Tesaro would have the necessary freedom to operate to permit it to exploit niraparib as it saw fit even if ultimately it did not exploit niraparib in all the ways whose use was claimed in the Licensed Patents. It was no more commercially irrational to behave in this way than it was to pay a royalty even though Tesaro entertained some doubt about the validity of the underlying patents. The broad licence brought with it commercial certainty.
139. Having obtained a broad licence, there was a question as to how royalties should be calculated. If there had been a clear dividing line between uses of niraparib that would infringe rights under the Licensed Patents and uses that would not, it

may well have been possible for AZ and Tesaro to agree a basis of charging royalties by reference only to infringing use. However, both parties would have been aware that the Licensed Patents were second medical use patents. The boundary between infringing and non-infringing use was uncertain not just because of the terms of the patents, but also because the question of whether use was potentially infringing or not might well depend on what took place in a doctor's consulting room or on the particular characteristics of a patient who had been prescribed Zejula. In those circumstances, there was nothing commercially irrational about agreeing a royalty based on total sales of Zejula which side-stepped all of the difficulties that would have been associated with a royalty charged on a "pay to infringe" basis that I have highlighted above.

Inferences based on "freedom to operate"

140. AZ argues that Tesaro's interpretation of the term "Compound" suffers from a fatal flaw in that, if it were correct, it would mean that Tesaro was not granted the freedom to operate that it needed. The basis of that argument is that the scope of the Licensed Patents was uncertain. If Tesaro was only granted a licence for uses of niraparib that actually infringed the Licensed Patents it would be running a commercial risk if it sought to develop niraparib for use that was not certain to infringe but might do so. AZ draws an analogy with situations where a person chooses to take a licence of a patent entertaining doubts as to the validity of the patent to protect against adverse consequences that might flow (for example injunctions restraining business activity) if no licence is taken but the patent is found to be valid.
141. I do not accept that submission. If Tesaro's argument is correct, then the Licence Agreement only gave it a licence to exploit niraparib in ways that would otherwise infringe the Licensed Patents. However, Tesaro did not need any licence broader than this. To the extent its use actually infringed the Licensed Patents, Tesaro could rely on its licence. To the extent its use did not actually infringe the Licensed Patents, Tesaro did not need a licence. Therefore, I do not accept that Tesaro's interpretation of the Licence Agreement would deprive it of the freedom to operate that it needed. The analogy with a licence under a possibly invalid patent is not apt. In such a case, a licensee would certainly need a licence if the patent turned out to be valid. However, Tesaro never needed a licence from AZ to use niraparib in ways that were not within the scope of the claims in the Licensed Patents.
142. However, I accept a more limited version of the submission. For the reasons I have given, Tesaro did not actually need a licence that extended beyond the claims made in the Licensed Patents. However, freedom to operate was an important issue for Tesaro at the time. Therefore, I am prepared to accept that the definition of "Compound" was expressed by references to uses that "may be" claimed or covered rather than uses that actually were claimed or covered to emphasise the width of the licence that was being granted. As I have explained, that emphasis was not necessary at least in the context of the definition of "Compound". However, even professionally drawn contracts are not always perfect and I conclude that both parties would have preferred "may be" to "is" to emphasise the width of the definition and so the width of the licence granted.

143. The point I have made in paragraph 142 does, therefore, lend some support to AZ's interpretation even though I have not accepted AZ's submission set out in paragraph 140. The width of definition that was being emphasised in the use of "may be" rather than "is" has a knock-on effect on the scope of the royalty payable which relied on the definition of "Compound" just as did the grant of the licence in section 3.2.

Inferences based on the terms of the Head Licence Agreements and AZ's averred "policy" (Issues 1.5 and 1.6)

144. My findings on Issues 1.5 and 1.6 mean that these matters shed little light on the proper interpretation of the Licence Agreement.

Inferences based on the doctrine of patent misuse (Issue 1.7)

145. Applying the principles set out in *Challinor and others v Bellis and Egan* set out in paragraph 15 above, I have concluded that a reasonable observer would consider both AZ and Tesaro to have a good understanding of the US law doctrine of patent misuse. To many people this would have been an obscure issue. However, both AZ and Tesaro were sophisticated business operators doing business in an area in which US patents, and the enforceability or otherwise of those patents, was of considerable importance. I will not treat them as having the kind of specialist legal knowledge of the area that Mr Belvis and Judge O'Malley have. However, they would have been aware that total sales royalties carried a risk of falling foul of the doctrine. They would also have been aware that one way to control that risk would be to include in the contract a statement that any total sales royalty was agreed for reasons of mutual convenience.

146. The factual matrix does, therefore, provide some indication that either i) the parties would not have wished to agree a total sales royalty because of the risk of patent misuse or ii) that if they had agreed such a royalty, they would have stated expressly in the contract that it was agreed for reasons of mutual convenience. That is a consideration of some weight that points against the interpretation of the Licence Agreement that I have set out above.

147. I have, however, concluded that this consideration is not sufficient to displace the inferences to be drawn from the ordinary language of the Licence Agreement for the following reasons.

148. First, the risk of the patent misuse doctrine applying was not so obviously high that it would be contrary to commercial common sense for the parties to agree a total sales royalty. There is no suggestion that the contractual negotiations involved Tesaro asking for a royalty calculated on a "pay to infringe" basis and AZ countering that only a total sales royalty was on offer. Moreover, an analysis of the draft Licence Agreements passing between the parties indicates that it was Tesaro who proposed the "may be claimed or covered" wording in the definition of "Compound" in place of the wording that AZ had suggested based on "is claimed or covered". I am far from saying that this change converted a "pay to infringe" royalty into a total sales royalty. However, Tesaro's suggested change to the drafting certainly did not make the royalty more likely to be read as a "pay to infringe" royalty. The parties could quite reasonably have concluded that the

fact that Tesaro had suggested this change did not indicate that it was seeking a “pay to infringe” royalty with a consequent reduction in the likelihood of the patent misuse doctrine applying.

149. Tesaro counters that Dr Barton’s emails referred to in paragraph 69 explained that AZ had “no room for manoeuvre which was at least suggestive of the kind of “conditioning” that could amount to patent misuse. I reject that argument. The absence of “room for manoeuvre” applied only to the financial terms. The only detail that she gave in that email about the royalty was to describe it as “small”. Her emails cannot fairly be read as signalling any refusal to accept royalties calculated on a pay to infringe basis or an insistence on a total sales royalty.
150. If the risk of patent misuse was obviously high then the absence of a statement in the Licence Agreement as to the “mutual convenience” of a total sales royalty would have assumed greater significance. However, since the risk could reasonably have been taken to be relatively low, it becomes less surprising that such a statement was not included.
151. I also agree with AZ that the Licence Agreement was a complex formal document drawn up with professional assistance following a process of negotiation. In those circumstances, I consider that the most reliable guide to the parties’ intentions is to be found in the wording of the provisions that they actually agreed. I have explained above why I consider the wording to support AZ’s interpretation of the agreement. Considerations of factual matrix, particularly relating to patent misuse, have given me pause for thought. However, particularly given that the parties could reasonably have concluded that the risk of patent misuse was relatively low, I have concluded that this indication from factual matrix is insufficient to disturb the inferences to be drawn from the language of the contract.

Conclusion on the question of interpretation

152. There is no suggestion that Tesaro has been selling Zejula for a purpose that includes anything other than as a treatment for cancer. In those circumstances, putting together all inferences, including those drawn from the wording of the Licence Agreement and those drawn from factual matrix, I have reached the conclusion that AZ’s answer to Issue 1 is to be preferred. Tesaro is obliged to pay AZ royalties on all net sales of Zejula in each country in which there are Licensed Patents from the first commercial sale in that country.