Neutral Citation Number: [2024] EWCA Civ 78

Case No: CA-2023-000866

IN THE COURT OF APPEAL (CIVIL DIVISION)
ON APPEAL FROM THE HIGH COURT OF JUSTICE, BUSINESS AND PROPERTY COURTS OF ENGLAND AND WALES, BUSINESS LIST (ChD)
Mr Justice Richards
[2023] EWHC 803 (Ch)

Royal Courts of Justice
Strand, London, WC2A 2LL

Date: 9 February 2024

Before :

LADY JUSTICE KING
LORD JUSTICE ARNOLD
and
LORD JUSTICE BIRSS

- -

Between :

ASTRAZENECA UK LIMITED	**Claimant/ Respondent**
- and -	
TESARO, INC.	**Defendant/ Appellant**

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- -

Conall Patton KC and Tom Mitcheson KC (instructed by **Linklaters LLP**) for the **Appellant**
Alan Maclean KC and Katherine Moggridge (instructed by **Freshfields Bruckhaus Deringer LLP**) for the **Respondent**

Hearing date : 17 January 2024

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Approved Judgment

This judgment was handed down remotely at 10.30am on 9 February 2024 by circulation to the parties or their representatives by e-mail and by release to the National Archives.

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Lord Justice Arnold:

Introduction

1. The issue on this appeal is the interpretation of two patent sub-licences dated 4 October 2012 ("the Licence Agreements") between the Claimant ("AZ") as licensor and the Defendant ("Tesaro") as licensee. AZ entered into the Licence Agreements pursuant to two licences ("the Head Licences") granted by the respective owners of the relevant patents ("the Licensed Patents"), the University of Sheffield ("Sheffield") and the Institute of Cancer Research ("ICR"), dated 25 July 2004 and 18 November 2004. AZ is the successor in title to KuDOS Pharmaceuticals Ltd, which was the original licensee under the Head Licences.

2. The Licensed Patents claim second medical uses of, or methods of treatment using, existing compounds within the class of drugs known as PARP inhibitors. One such drug is niraparib. Niraparib is protected by other patents claiming the compound itself, which Tesaro has licensed from Merck. It was known prior to 2003 (the priority date of all the Licensed Patents) that PARP inhibitors could be used to treat cancer in conjunction with other DNA-damaging treatments such as radiotherapy and chemotherapy. The claims of the Licensed Patents are based on the discovery that PARP inhibitors could be used on their own as a treatment for cancer by targeting the homologous recombination ("HR") pathway for DNA repair. If a cancer cell is HR-deficient ("HRD"), breaks in DNA arising as a result of the administration of a PARP inhibitor may go unrepaired leading to the death of the cell. HRD cancer cells are more likely to be found in individuals who have the BRCA1 or BRCA2 gene mutations, but this is not guaranteed.

3. In 2017 Tesaro obtained marketing authorisations from the US Food and Drug Administration and the European Medicines Agency to market niraparib under the brand name Zejula as a treatment for ovarian, fallopian tube and primary peritoneal cancer in women. (The terms of the two marketing authorisations are in fact a little more nuanced than this, and they differ from each other in certain respects, but for present purposes nothing turns on these details.) Tesaro contends that only a minority of sales of Zejula are for uses or treatments falling within the scope of the claims of the Licensed Patents. AZ does not dispute that some sales are, or at least may be, outside the scope of the Licensed Patents, but there are substantial issues between the parties as to what the respective percentages are and how those percentages are to be determined.

4. Tesaro contends that under the terms of the Licence Agreements it is only obliged to pay AZ royalties in respect of sales of Zejula for uses or treatments that do fall within the scope of the claims of the Licensed Patents. Richards J held that the Licence Agreements require Tesaro to pay a royalty calculated by reference to total sales of niraparib for use as cancer treatments for the reasons he gave in his judgment dated 5 April 2023 [2023] EWHC 803 (Ch). Since Zejula is not sold otherwise than for use as a cancer treatment, the effect of this interpretation is that Tesaro must pay royalties on all net sales of Zejula in each country where at least one Licensed Patent subsists. Tesaro appeals against this conclusion.

5. It is common ground that the issue is to be resolved by applying normal principles of contractual interpretation. There is no dispute as to those principles, which were

accurately summarised by the judge at [12]-[18]. It is therefore unnecessary to set them out again.

The factual matrix

6. The judge made detailed findings as to the relevant factual matrix at [21]-[107]. The findings which are relevant for the purposes of the appeal, in addition to those mentioned in paragraph 2 above, can be summarised as follows.

7. 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 nevertheless likely to be HRD; and (iii) even more broadly in patients who had not been identified as HRD.

8. Use (i) was, as Tesaro recognised, likely to be within the scope of the claims in the Licensed Patents. Tesaro 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 believed that some aspects of use (iii), which included using niraparib in conjunction with chemotherapy, would not infringe the Licensed Patents. Tesaro's belief that some of the uses of niraparib that it was considering would involve no infringement of the Licensed Patents was appropriately grounded in the wording of those patents as they would be read by an oncologist.

9. 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 of 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 Sheffield and ICR made important contributions to cancer research, so it was appropriate for them to obtain reward for that. Tesaro therefore decided not to challenge the validity of the Licensed Patents, but instead to seek licences under them which would give it freedom to operate. In addition to taking a licence in respect of niraparib, Tesaro took a licence in respect of another Merck compound called Mk-2512 as back-up to niraparib.

10. 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 found out whether niraparib could be developed profitably as hoped.

11. The judge did not, at least explicitly, find that the facts I have summarised in paragraphs 7-10 above were also known to AZ, but it is implicit in his reasoning, and I do not understand it to be in dispute, that those facts were reasonably available to AZ. Although AZ was not privy to the precise details of Tesaro's plans for niraparib, Tesaro had published an outline of those plans in a prospectus for the initial public offering of its shares issued on 27 June 2012. AZ would have appreciated that some

uses of niraparib would fall within the Licensed Patents while others would not. It would also have appreciated that it was open to Tesaro to challenge the validity of the Licensed Patents rather than taking a licence. It would also have appreciated that successful development of niraparib as a sole treatment for any form of cancer was far from guaranteed.

12. Before Tesaro signed the Licence Agreements, AZ provided Tesaro with copies of the Head Licences with the details of the royalties payable to ICR and Sheffield redacted. The judge found that the parties did not proceed on the basis of any common understanding that royalties were payable by AZ under the Head Licences only in respect of sales of PARP inhibitors for uses and treatments covered by the Licensed Patents. As will appear, however, the Head Licences are cross-referenced in the Licence Agreements.

13. During the course of negotiations over the terms of the Licence Agreements, Dr Emma Barton of AZ sent emails to Tesaro's solicitors about proposed terms on 23 May 2012 and 2 June 2012. In the first she stated that "[t]he financials have been set [s]o 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". In the second email she made a very similar statement with respect to Sheffield. The judge found that these emails set out a negotiating position, and that the parties did not proceed on the basis of any common understanding as to the policy adopted by AZ in setting the royalty payable under the Licence Agreements.

14. The judge received expert evidence adduced by the parties concerning a doctrine of US patent law known as "patent misuse" as it stood in 2012. The judge made findings based on that evidence at [82], the key points being as follows:

> "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.
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> 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.
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> 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.
>
> …

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.

…

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….

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 … 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 …. 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 relevant terms of the Licence Agreements

15. The Licence Agreements are in largely identical terms, and it is sufficient to refer, as the judge and the parties did, to the terms of the Licence Agreement relating to Sheffield's patents. It is common ground that the Licence Agreements are professionally drafted contracts between sophisticated commercial parties.

16. The Licence Agreement begins with four recitals. Recitals A and D state:

> "(A) WHEREAS, Under the terms of a Licence and Collaboration Agreement dated 25th July 2004 and made between to KuDOS Pharmaceuticals Limited … and the University of Sheffield … (the '**KuDOS Agreement**'), Sheffield granted KuDOS the exclusive worldwide rights (including the right to grant sublicences) to use the Patents Rights (as defined in the KuDOS Agreement) to develop and sell any compound which has been demonstrated to inhibit poly (ADP-ribose) polymerase (PARP), the manufacture, formulation, use of or method of treatment of which is covered by a Valid Claim in the Patent Rights;
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> …
>
> (D) WHEREAS, TESARO desires to obtain from AstraZeneca, and AstraZeneca is willing to grant to TESARO, an exclusive licence under the above-mentioned Patent Rights to develop and commercialise its proprietary pharmaceutical compounds niraparib and MK-2512 for the inhibition of PARP for the treatment of cancer in the Field, all in accordance with the terms and conditions set out below in this Agreement;".

17. Clause 3.2 contains the licence granted by AZ:

> "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."

18. Clause 5.3 contains Tesaro's obligation to pay a royalty. So far as relevant, this provides:

> "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 specified percentage] of the aggregate Net Sales of Licensed Products in the Territory ... 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."

19. Clause 5.5 sets out the term of the obligation to pay a royalty:

> "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."

20. All three clauses refer to "Licensed Product". This is defined in clause 1.29 as "the Product and the Combination Products". The Combination Products can be ignored. "Product" is defined in clause 1.46 as "any product in a form suitable for human applications that contains the Compound as the sole active ingredient".

21. Thus the critical definition is that of "Compound". This is defined in clause 1.11 as:

> "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 dispute between the parties is as to the meaning of the words I have italicised in this definition ("the italicised words"), and in particular the words "may be".

22. The "Licensed Patents" are defined in clause 1.28 (taking into account the definition of "Patents" in clause 1.43) as the granted patents and pending applications listed in Schedule 1.

Interpretation of the Licence Agreements

23. As I have said, the dispute between the parties is as to the scope of Tesaro's royalty obligation in clause 5.3 of the Licence Agreements. For the reasons I have explained, this depends on the definition of "Compound". Tesaro contends that the effect of the italicised words is to limit the scope of the obligation to sales of niraparib for uses or treatments falling within the scope of the claims of the Licensed Patents. AZ disputes this.

24. It is convenient before proceeding further to address a basic point about patent licences and royalty obligations. A licensee of a patent only ever needs a licence to do acts which would otherwise infringe the patent. No licence is needed to do acts which would not infringe anyway. Thus it is axiomatic that the scope of the licence should in principle be coextensive with the scope of the claims of the patent. I say "in principle" because the purity of the principle is complicated by various points, including the following. First, the scope of the claims may be unclear, for example because they are difficult to interpret or because of the impact of doctrines such as the doctrine of

equivalents. Secondly, the licensee only needs a licence in respect of valid claims, and granted claims may turn out not to be valid. Both the scope of protection and validity may take a lengthy and expensive court battle to determine. Thirdly, the licence may cover a number of different territories, and the patent coverage may vary from territory to territory. Fourthly, the licence may cover patents which expire at different times. For these reasons licences may be agreed the scope of which, upon analysis, extends beyond what the licensee strictly needed.

25. Even if the scope of the licence is indeed coextensive with the scope of the claims of the licensed patent, however, it does not necessarily follow that the scope of royalty obligation should be coextensive with the scope of the claims. In some circumstances it may be perfectly rational for the parties to agree to a royalty obligation which extends beyond the scope of the claims of the licensed patent. For example, in some circumstances the parties may agree that it would be too burdensome to try to determine which sales of a product fall within the claims and which do not, and that it would be simpler for both parties if a royalty was paid on all sales of the product, with the royalty rate being set at a level which reflects the fact that some sales do not fall within the claims. It can be seen that this consideration is reflected in the US patent misuse doctrine.

26. It follows that it would be wrong to approach the dispute in the present case on the basis of any presumption that the scope of the royalty obligation is likely to be coextensive with the scope of the Licensed Patents. The question is what the scope of royalty obligation actually agreed between the parties is. That question must be resolved by interpreting the wording agreed by the parties to delineate the royalty obligation.

27. That said, in my judgment Tesaro's interpretation of the Licence Agreements is the correct one. My reasons are as follows.

28. First, an important feature of the architecture of the Licence Agreements is that the same definitions are employed in clause 3.2 and in clause 5.3. As I have explained, both depend on the definition of "Compound". Thus the scope of the licence granted and the scope of the royalty obligation are both governed by that definition, and in particular by the italicised words. At least at first blush, the purpose of those words in the context of the grant of the licence is to align the scope of the licence with the scope of the claims of the Licensed Patents. If that is their effect in the context of the grant of the licence, then they have the same effect in the context of the royalty obligation. In other words, this is not a case where the parties have used materially different words to define the scope of the royalty obligation to those used to define the scope of the licence.

29. Secondly, it is necessary to give the italicised words some meaning and effect. They were obviously included for a purpose, particularly given that they govern both the scope of the licence and the scope of the royalty obligation. It would therefore be wrong to interpret them as having no effect. As I have said, their apparent purpose is to align the scope of the licence and the scope of the royalty obligation with the scope of the claims of the Licensed Patents. It is not apparent what other purpose they could be intended to serve.

30. Thirdly, this reading is supported by clauses 5.5.1 and 5.5.2. These provide that the obligation to pay royalties to AZ (in a country where the First Commercial Sale pre-dates the grant of a Licensed Patent) starts when a Patent is granted that "covers or claims" the Exploitation of the Licensed Product (clause 5.5.1) and ceases when "there is no longer any Valid Claim that covers or claims" such Exploitation (clause 5.5.2). The temporal scope of the royalty obligation is thus circumscribed at both ends by whether a granted Patent in a given country "covers or claims" the Exploitation of the Licensed Product. It makes sense that the same touchstone should apply to the subject matter scope of the royalty obligation.

31. Fourthly, the judge thought that the use of the words "may be", rather than "is" or "will be", militated against Tesaro's interpretation, but I disagree. The wording is a little surprising, but I agree with Tesaro that "may be" can be, and in this case should be, interpreted as connoting futurity. The use of prospective language is understandable for two reasons. First, the fact that some of the Licensed Patents had not been granted and it was uncertain whether they would ever be granted, and if so with what scope. Secondly, Exploitation by Tesaro was some way off and would depend on successful development of niraparib to the point that it received regulatory authorisation.

32. AZ argued before the judge that "may be" connoted some probability that niraparib sold by Tesaro would be used in a manner which turned out to be covered by a claim of a Licensed Patent. The judge rejected this argument on the ground that no minimum likelihood is stated as being necessary to satisfy the "may be" threshold. AZ did not serve any respondent's notice seeking to revive this argument. On the contrary, AZ filed a skeleton argument supporting the judge's interpretation. Despite this, during the course of argument counsel for AZ submitted that "may be" covered any possibility that niraparib sold by Tesaro might be used in a manner covered by a Licensed Patent and that a 0.1% probability would suffice for this purpose. This is a bizarre interpretation of the italicised words, and one which is commercially irrational. The judge was right to reject it.

33. The judge devised his own interpretation of the italicised words, which was that they distinguished between sales of niraparib for use as a cancer treatment and sales of niraparib for other uses such as for use as a treatment for hair loss. There are two problems with this interpretation. The first and most obvious is that it has no foundation in the words used by the parties. If the parties had intended that royalties would be payable upon any sales of niraparib for use as a cancer treatment, it would be easy for them to say so, but they did not. The second problem is that the judge's interpretation involves AZ granting a licence which it had no power to grant under the Head Licences and Tesaro taking a licence of a breadth which it plainly did not need. This is highly improbable.

34. Counsel for AZ emphasised the difficulty of deciding whether or not second medical use claims are infringed, and in particular whether the claims of the Licensed Patents that are second medical use claims are infringed. It is not necessary for the purposes of this judgment to explain what these difficulties are. It is sufficient to say that I entirely accept that experience has shown that they are very real ones. (Although it is perhaps debatable to what extent those difficulties would have been known to the parties in 2012, this is not a question which appears to have been investigated in evidence before the judge, and I shall therefore assume that the parties were alive to

the potential problems.) It would therefore not have been surprising if the parties had agreed a royalty obligation which did not depend on the resolution of such difficult questions. This could have been done in a number of ways. The parties could, for example, have agreed that royalties would be payable on all sales of niraparib, or on all sales of niraparib for use as a cancer treatment, or on all sales of niraparib for use as a stand-alone cancer treatment, or on all sales of niraparib for indications covered by a relevant marketing authorisation. But they did none of these things. Instead, they aligned the scope of the royalty obligation with the scope of the licence, and they linked both to the scope of the claims of the Licensed Patents.

35. Fifthly, the judge also thought that the absence of any provision in the Licence Agreements specifying how it was to be determined whether sales of niraparib were for uses or treatments that fell within the scope of the claims of the Licensed Patents so as to give rise to royalties militated against Tesaro's interpretation, but again I disagree. Tying the scope of the royalty obligation to the scope of the licensed patent(s) can give rise to difficulty and dispute, but it is nevertheless common for patent licences not to contain any mechanism for ascertaining the extent to which the royalty is due beyond that provided by patent law. Where this is thought likely to cause serious problems, the usual solution is to agree a royalty obligation that is independent of the scope of the claims of the patent(s) as discussed above. Otherwise one is liable to substitute one problem for another. As I have already said, it would not have been surprising if the parties had taken that course in this case, but they did not.

36. Sixthly, it is a well-established principle of interpretation that, where the words of a contract are capable of two meanings, one of which is lawful and the other unlawful, the former interpretation is to be preferred: see Lewison, *The Interpretation of Contracts* (8th ed) at 7.119-7.125. On Tesaro's interpretation the Licence Agreements do not contravene the US patent misuse doctrine, whereas on AZ's interpretation there is a serious risk that they would do so given that they do not contain any statement to the effect that the scope of the royalty obligation has been framed for the mutual convenience of the parties, nor is there any evidence that mutual convenience was the reason for the adoption of the italicised words. The judge accepted that this was a factor which favoured Tesaro's interpretation, but concluded that it was insufficient to displace his interpretation of the wording in question.

37. Seventhly, it is common ground that, given that the recitals to the Licence Agreements expressly cross-refer to the Head Licences and make it clear that the Head Licences are the source of AZ's ability to grant the sub-licences of the Licensed Patents in the Licence Agreements, the Head Licences may be referred to in order to resolve any ambiguity in the Licence Agreements. It is not necessary to set out all of the relevant terms of the Head Licences. It is sufficient to record that, taking the Sheffield Head Licence, clauses 6.4 and 6.5 require AZ to pay Sheffield a proportion of Net Sales for so long as there are Valid Claims of University Patent Rights Covering the PARP Inhibitor in the Product in question in the country of sale. "PARP Inhibitor" is defined in clause 1.1.42 as a Compound which is "Covered by Valid Claims of University Patent Rights". "Cover" and cognate terms are defined in clause 1.1.14 as meaning that the making, use, etc of a given product "would infringe a Valid Claim of a Patent Right in the absence of a licence".

38. Tesaro contends that the wording of the Head Licences makes it clear that the scope of the royalty obligation is coextensive with the scope of the claims of the Patent

Rights (i.e. the Licensed Patents), but the Head Licences do not contain any contractual mechanism beyond that provided by patent law for determining when sales of PARP Inhibitors are royalty-bearing and when they are not. Counsel for AZ advanced no contrary interpretation of the Head Licences.

39. Tesaro further contends that this supports its interpretation of the Licence Agreements. Counsel for AZ disputed this, and emphasised the difference in wording between the Head Licences and the Licence Agreements, with the former saying "would infringe" and the later saying "may be". I accept that there is a difference in the wording. Nevertheless it seems to me that the reasonable reader of the Licence Agreements who was uncertain what was meant by the words "may be" in the definition of "Compound", and looked at the Head Licences to see if they shed any light on the question, would conclude that the two sets of agreements were intending to express the same idea in slightly different words.

40. Lastly, this reading of the relationship between the scope of the royalty obligation in the Head Licences and the scope of the royalty obligation in the Licence Agreements is supported by Dr Barton's emails. This is not a point which depends on a common understanding of the parties. Rather they are factual statements made by one party to the other about the relationship between the two sets of the agreements which are therefore available to the reasonable reader interpreting the Licence Agreements. Counsel for AZ pointed out that Tesaro had not seen the Head Licences at the time those statements were made, but that is irrelevant. Moreover, Tesaro did see the Head Licences before signing the Licence Agreements, and the Licence Agreements are to be interpreted as at the date they were entered into. Dr Barton said that the downstream royalties matched the upstream royalties, which would only be the case if the two sets of agreements had royalty obligations of the same scope.

Conclusion

41. For the reasons given above I would allow the appeal.

Lord Justice Birss:

42. I agree that the appeal should be allowed, and I agree with almost all of the reasons for allowing the appeal given by Arnold LJ. However there is one aspect on which I differ. It relates to the fourth reason given by my Lord (and the fifth reason, which relates to it). Since this makes no difference to the end result, I only need explain the matter briefly.

43. The issue is what the expression "the use of which may be claimed or covered by *[...]* the Licensed Patents" in the definition of Compound would be understood to mean on ordinary principles of construction. At first sight a phrase of this kind, which refers to the reason why you might do something with a thing, is an odd expression to find in a definition of the thing itself (a compound). The answer, as my Lord has explained, is that the patents in this case were or would be based on second medical uses of, or methods of treatment with, known compounds. This idea, of purpose limited patent claims to products, is and was an area of conceptual difficulty and real legal doubt well before these licences were negotiated (see e.g. the House of Lords in *Merrell Dow v Norton* [1995] UKHL 14). The sophisticated pharmaceutical companies who are parties to these contracts will have been well aware of that. Exactly what patent

claims of this kind meant and what acts infringed them was uncertain and raised real problems. One further example will suffice. In *Lilly ICOS v Pfizer* [2000] EWHC Patents 49 Laddie J at [40] accepted a submission that the meaning of the words "for treating cancer" in this context had two aspects. They meant suitable for *trying* to treat cancer (my emphasis) and they required that treatment to be successful, in at least some individuals (not all). Further uncertainty arises from the fact that use claims were essentially European, while the USA permitted methods of treatment claims which raised different tricky issues.

44. The words in issue clearly relate to the idea of patents claiming uses of the compounds, and I therefore sympathise with the judge below, who was faced with interpreting these words in this tricky context.

45. I believe there is more merit in the judge's conclusion (that royalty is due on all sales where the product is used for cancer) than there might seem, and also that his approach is not as far away from AZ's submissions as it might appear. For one thing the judge certainly thought he was preferring AZ's interpretation (see e.g. [2] and [152]).

46. It is true that the words of the clause do not mention "cancer", and so in a literal sense the judge's approach cannot be based on those words. But I think if there was a flaw here it was that the judge's reasoning was just a bit too compressed. Although he never said so in terms, I think that by characterising it this way the judge was explaining what the consequence of the construction he had arrived at would be on the facts of this case, rather than saying that that is what the words of the clause actually meant.

47. As I read the judgment the judge agreed with Tesaro (at [131]) that the words "may be" were not referring to a measure of probability. Therefore the words were not there to say, for example, that if there was a 50% chance (or 10% or whatever %) that a given use would later be claimed in a patent then it was covered by the definition, and if the chance was lower than that threshold then not. If that was AZ's construction then the judge was rejecting it, but I do not think it was AZ's construction below and certainly was not how they explained their construction in this court. After rejecting the "pure probability" approach in [131], in the last sentence of that paragraph the judge said "However, it is possible to read the words 'may be' as referencing a different kind of possibility" and he went on in [132] to [136] to analyse that and conclude at the start of [136] that "I consider that AZ's interpretation is much the better having regard to the words of the agreement" before going on to examine the factual matrix and see what influence it had, if any.

48. So what was the judge's construction of the clause? I think what the judge held that the words "may be" referred to was the existence, at the time of the contract, of a possibility that the use could or might be claimed (see the last sentence of [131]). One might add, although the judge did not, that as long as the possibility of the use being claimed was not wholly fanciful, then it was covered. That is not exactly how counsel for AZ put it before this court when questioned from the bench, but it amounts to much the same thing. One cannot express this in percentage terms. Nevertheless in my judgment, put this way both parties would be able to see there was genuinely a *possibility* that uses for various sorts of cancers may be claimed in various ways, without being able to predict the details, while equally agreeing that there is no

possibility whatever that a use as, say, a hair loss treatment may be claimed in the Licensed Patents. Hair loss is the example the judge gave at [133].

49. There may well be forms of cancer for which one could say there was no possibility of a use for that cancer being claimed in these patents down the line, but nevertheless to describe the clause as covering use for cancer, as the judge did, is still a reasonable summary of the effect of the words applied to the facts of this case.

50. This result would mean that all of Tesaro's current uses would attract a need to pay a royalty since, as I understand the submissions, they are all based on the treatment rationale of using a PARP inhibitor like niraparib to target the HR pathway in cancer. By avoiding many of the tricky patent claim issues these kinds of inventions give rise to, this construction would greatly simplify the determination of the amount of royalty to be paid, which is not a trivial advantage, in my judgment.

51. However, while I think the judge's approach is tenable, I do agree with my Lord that overall Tesaro's construction is to be preferred given the combined strength of the first, second, third, sixth and seventh reasons given by Arnold LJ. In the end I think AZ's approach is a clever way of trying retrospectively to make the words fit the result they would like to achieve. I do not believe that is what an objective reader of the clause, in the relevant commercial context at the time, would think it meant.

52. Indeed I believe the sixth reason (risk of patent misuse doctrine coming into play) is a particularly important point favouring Tesaro because the judge's interpretation has the result that sales which would not require a licence at all would still attract a royalty. This point can be overplayed, as my Lord has explained, because in a patent licence the definition of the royalty bearing event may very well not be co-extensive with the scope of the licence itself and for good reasons (for an example well away from the facts of this case see *Unwired Planet v Huawei* [2015] EWHC 1029 (Pat) at [51]-[52]). However in the present case that consideration has real force.

53. I would allow the appeal.

Lady Justice King:

54. I would also allow the appeal.

55. I do not think it is necessary for me further to analyse Arnold LJ's reason four given that the outcome of the appeal is in no way reliant upon the interpretation placed upon the words 'may be' by either Arnold LJ or Birss LJ. For my part, in common with Birss LJ, I regard the sixth reason (risk of patent misuse doctrine coming into play) as of particular importance on the facts of this case.