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Case Nos: HP-2021-000031

IN THE HIGH COURT OF JUSTICE
BUSINESS AND PROPERTY COURTS OF ENGLAND AND WALES
INTELLECTUAL PROPERTY LIST (ChD)
PATENTS COURT

Rolls Building
Fetter Lane
London, EC4A 1NL

15 November 2024

Before :

THE HON MR JUSTICE MELLOR

Between :

(1) SANDOZ AG
(2) SANDOZ LIMITED
(3) SANDOZ GMBH
(4) POLPHARMA BIOLOGICS SA
- and -
BIOGEN MA INC

Claimants

Defendant

KATHRYN PICKARD and THOMAS LUNT (instructed by **Bristows LLP**) for the
Claimants

JUSTIN TURNER KC and TOM ALKIN (instructed by **Powell Gilbert LLP**) for the
Defendant

Hearing date: 7th November 2024

APPROVED JUDGMENT

This judgment was handed down remotely by circulation to the parties' representatives by email. It will also be released for publication on the National Archives and other websites. The date and time for hand-down is deemed to be Friday 15 November 2024 at 10am.

THE HON MR JUSTICE MELLOR

Mr Justice Mellor:

INTRODUCTION

1. My judgment from the trial of this action was handed down on 11 October 2024. At the form of order hearing last Thursday (7 November), I refused Biogen's application for permission to appeal. This judgment deals with the remaining issues on which I heard argument, principally the costs of the action with subsidiary argument on whether certain documents should remain confidential. Due to time constraints last Thursday but also because I wanted to review my trial judgment and parts of the expert evidence, unusually I reserved my judgment.

COSTS

Applicable principles

2. There was no dispute as to the principles I should apply.
3. The Court has a wide discretion as to whether to make a costs order and, if so, as to what order to make (CPR 44.2(1)). The general rule is that the unsuccessful party will be ordered to pay the costs of the successful party (CPR 44.2(2)(a)). The Court will have regard to all the circumstances including the conduct of the parties (CPR 44.2(4)). Conduct includes matters such as whether it was reasonable for a party to raise, pursue, or contest a particular allegation or issue and the manner in which a party has pursued or defended its case or a particular allegation or issues (CPR 44.5).
4. Both sides referred to my judgment in *Lifestyle Equities v Berkshire Polo Club* [2023] EWHC 2923 (Ch), where I reiterated the approach to adopt when considering what costs award to make. At [35] I set out the three questions commonly asked in IP matters when considering whether to make an issue-based costs award:

(a) Who is the overall winner? There is then the assumption that the overall costs should be awarded to the winner.

(b) Are there any suitably circumscribed issues which it is appropriate in the circumstances for the winner to be deprived of their costs of?

(c) Is it appropriate to go further and award the losing party their costs of that issue from the winning party?

5. At [39], I also referred to the following summary from *Pigot v Environment Agency* [2020] Costs LR 825 at [6]:
 - (1) The mere fact that the successful party was not successful on every issue does not, of itself, justify an issue-based cost order...
 - (2) Such an order may be appropriate if there is a discrete or distinct issue, the raising of which caused additional costs to be incurred. Such an order may also be appropriate if the overall costs were materially increased by the

unreasonable raising of one or more issues on which the successful party failed.

- (3) Where there is a discrete issue which caused additional costs to be incurred, if the issue was raised reasonably, the successful party is likely to be deprived of its costs of the issue. If the issue was raised unreasonably, the successful party is likely also to be ordered to pay the costs of the issue incurred by the unsuccessful party...
 - (4) Where an issue based costs order is appropriate, the court should attempt to reflect it by ordering payment of a proportion of the receiving party's costs if that is practicable.
 - (5) An issue based costs order should reflect the extent to which the costs were increased by the raising of the issue; costs which would have been incurred even if the issue had not been raised should be paid by the unsuccessful party.
 - (6) Before making an issue-based costs order, it is important to stand back and ask whether, applying the principles set out in CPR r.44.2, it is in all the circumstances of the case the right result. The aim must always be to make an order that reflects the overall justice of the case.
6. Both sides reminded me of this passage from the judgment of as Birss J (as he then was) in *Unwired Planet v Huawei* [2016] EWHC 410 (Pat) at [5], on what amounts to a 'suitably circumscribed issue':

"One issue is: what is a suitably circumscribed issue? Or in other words, at what level of generality or granularity is that matter to be decided? Plainly it will vary from case to case. Often in patent cases one kind of suitably circumscribed issue and appropriate level of granularity is taking things at the level of individual cited items of prior art, but that is not a hard and fast rule. It is possible for a suitably circumscribed issue to arise within a broader category. An example of this was the Court of Appeal in *ConvaTec Technologies Inc v Smith & Nephew plc* [2015] EWCA 803 (Civ). Here, instead of dealing with the costs at the level of the issue of infringement as a whole, the court made a special order relating to experiments which formed part of the infringement case."

7. Finally, Biogen drew attention to the wise words of Henry Carr J in *F&C Alternative Investment (Holdings) Ltd v Barthelemy* [2012] EWCA Civ 843 on the meaning of the phrase 'suitably exceptional' which was used in some earlier formulations of the third question i.e. when it might be appropriate to award costs to be paid by the successful party. Henry Carr J explained:

"In my view, this apparent dichotomy may be resolved by a proper understanding of the phrase "suitably exceptional". It is intended to indicate that if the unsuccessful party succeeds on a particular issue, that is not, on its own, sufficient to award costs against the successful party. There must be something which makes it appropriate and just to order not only that the successful party does not recover his costs, but also that it should pay the costs of the relevant issue. On the other hand,

it is not intended to imply that such awards of costs will be extremely rare. Where there is a discrete issue, which required substantial expenditure of costs, it may be just in all the circumstances to order payment of costs.'

Application of the principles

Question 1: who is the overall winner?

8. Unsurprisingly, there was no dispute that Sandoz were the overall winner, so the starting point is that Sandoz are entitled to their costs.
9. Sandoz's total costs (including post-trial costs) amounted to £2.454m. I was provided with no overall figure for the costs incurred by Biogen.

Question 2: are there any suitably circumscribed issues on which it is appropriate for the Claimants to be deprived of their costs?

10. This was the main area of dispute. In their evidence in chief filed for this hearing (French 2), Sandoz conceded that it was appropriate to deduct 8.2% of their overall costs from their total to reflect the respects in which Sandoz did not succeed on certain issues. Biogen responded with an analysis (in Gilbert 4) that the deduction should be considerably greater – 43% or a deduction of just over £1m of costs. Having considered Biogen's arguments, Ms French filed her reply statement (French 3) which proposed a total deduction of up to 12.3%, should Sandoz's primary positions not be accepted.
11. These proposed deductions were analysed and argued under 7 heads, and were summarised in this table.

Deduction to Sandoz/Polpharma's total costs	Sandoz/Polpharma primary position		Biogen position		Sandoz/Polpharma response to Biogen's position	
Technical infringement	0%	-	6%	£139,990.40	2%	£46,663.45
Declaratory relief	2%	£46,663.45	3%	£69,995.18	2%	£46,663.45
Obviousness	6%	£139,990.36	25%	£583,293.15	6%	£139,990.36
Unpatentable subject matter	0%	-	1%	£23,331.73	0.5%	£11,665.86
Dr Dugan	0%	-	8%	£85,549	1.6%	£36,274.88
US lawyers' fees	0.2%	£3,552.53		£8,028	0.2%	£3,552.53
Counsel fees	0%	-		£109,209.25	0%	-
Total deductions	8.2%	£190,206.34	43%	£1,003,264.22	12.3%	£284,810.53
Amount payable		£2,142,966.27		£1,329,908.39		£2,048,362.08
Interim payment (70%)		£1,500,076.39		£930,935.87		£1,433,853.45

12. There are some points to note about this table. First, the totals are changed by the inclusion of Sandoz's post-trial costs, a point which will be taken into account later. Second, the Sandoz response column does not necessarily represent agreed deductions – under a number of heads Sandoz's primary position was that no deduction was appropriate at all. So, at first sight, it might appear that because Sandoz engaged with each of the 7 heads of proposed deduction no point was taken that any of them was not a suitably circumscribed issue, but that would be incorrect. Third, by far the greatest deduction proposed by Biogen was in relation to obviousness. Biogen contended that Sandoz suffered a straight loss on obviousness, that this was unaffected by any other issues, and that a deduction of 25% of Sandoz's costs should be the consequence.

Sandoz's position was more nuanced, but they conceded a 6% deduction would be appropriate.

13. To determine this and certain of the other issues requires an analysis of the structure of this case and the extent to which the various issues interacted.
14. Both sides served evidence for this Form of Order hearing. For Sandoz, Ms French provided (i) a reminder of some of the events which occurred in this litigation which might not have been centre of mind at trial, (ii) an analysis of the costs incurred by Sandoz, (iii) an analysis of the issues decided in my judgment, (iv) a commentary on how various issues interacted, including the costs deductions proposed by Biogen in correspondence and (v) explanation of why the documents presently the subject of a CPR31.22 Order should remain confidential.
15. For Biogen, Dr Gilbert explained the costs deductions proposed by Biogen in greater detail. She relates the results of a paragraph counting exercise conducted by an associate and a paralegal at Powell Gilbert of the expert evidence, the Skeletons and the Judgment on four of the costs issues, dubbed Technical Infringement, Declaratory Relief, Obviousness and Unpatentable Subject-Matter. On the basis of that and her overall assessment of the amount of time taken to address each of these issues, she states her view of the appropriate deduction.
16. The other three areas of proposed deduction are Dr Dugan's evidence (on which Biogen also seek payment of their costs), Foreign Lawyer's Fees and the cost of Sandoz' third counsel.
17. Ms French responded in her third witness statement, in which she acknowledged the force of some of the points made by Dr Gilbert, accepted a deduction in relation to US lawyer fees and proposed that the total deductions to Sandoz's costs should rise from the initial 8.2% to at most 12.3%.
18. As usual, I have taken account of the paragraph counting exercises only to *some* extent, recognising their inherent limitations. An issues-based costs order has to be the product of impressions formed by the judge as to the weight and costs burden of particular issues, along with an overall cross-check that the result appears fair.

Analysis of the issues

19. This was an unusual case in which the correct construction of the claim underpinned most of the issues at trial. Although Biogen now say their preferred construction was always what I termed 'Construction 3' (or, to be precise, *essentially* Construction 3), I have the impression that this has firmed up with the benefit of hindsight and knowledge of how various issues were determined in my judgment. Furthermore, the notion that Biogen ran this case consistently does not sit well with the observation that Biogen said nothing about construction in their Opening Skeleton Argument (as I recorded at [263]). At best, Biogen were being careful to hedge their bets.
20. Biogen also contested that they ever ran what I termed Constructions 1, 2 and 4 as constructions of claim 1. However, I found Biogen's case on construction to be extremely slippery which is why I found it helpful to conduct the analysis of the six constructions in my trial judgment. Furthermore, in this case, it was important on a

number of issues not to use a mere precis of the claim, which is why I included Constructions 1 and 2. Although Dr Turner now says that Construction 4 was not advanced, but it merely represents how the Skilled Team is able to ‘work the Patent’, I confess I did not follow that distinction. In any relevant sense ‘working the Patent’ to me means implementing the invention in claim 1, which is why I included the median argument as Construction 4.

21. Perhaps the most significant difficulty with Construction 3 is the fact that the claim includes this specific cut-point at an index value of 1.5, the specification includes a significant amount of teaching as to how that index value was fixed, based on the extensive data cited, yet on Construction 3 there was, apparently, no need to include 1.5 in the claim at all, a point which was confirmed in this exchange during submissions on permission to appeal:

20 MR. JUSTICE MELLOR: Right. On Construction 3, the 1.5 value does

21 not mean anything, does it?

22 MR. TURNER: No.

23 MR. JUSTICE MELLOR: It is just saying let us have a division.

24 MR. TURNER: Yes. You can set 1.5 wherever you want.

22. In this regard, it is appropriate to mention one point advanced by Dr Turner when seeking permission to appeal. Biogen contended there was an internal inconsistency in my judgment because I rejected Construction 3 on the basis that the 1.5 value was arbitrary, yet the same point applied to Construction 5, which I adopted. This contention ignores two key differences between Constructions 3 and 5. First, Construction 5 takes account of the other explicit features of the ELISA in claim 1, whereas on Construction 3 they are deleted from the claim entirely. Second, it follows from that that the 1.5 value in Construction 5 is less arbitrary than in Construction 3. The final point to note is that the application of the well-known principles points clearly to Construction 5. Construction 3 is particularly difficult to justify in view of (a) point (vii) of the summary in *Virgin*, which shows Construction 3 cannot be correct, but also (b) because it is counterintuitive – why include the specific cut-point at the index value of 1.5 only for it to be ignored?
23. My attention was also drawn to an exchange of correspondence in the lead up to trial prompted by Biogen seeking to introduce their case on infringement by equivalence. Bristows’ letter of 29 September 2023 made the point that Biogen’s position on construction remained unclear, not least because the ‘inventive core’ used by Biogen in their equivalence pleading was framed at a high level of generality and stripped out a number of features of the assay which were explicitly specified in claim 1. The response from Powell Gilbert is dated 7 November 2023. With the benefit of hindsight, the response does appear to argue Construction 3 (but there is also mention of the median argument) and I can also see the point acknowledged by Dr Turner in the extract above, that the 1.5 value is meaningless and/or can be ignored, because the same range of titres could be expressed via different index values.
24. A principal argument which Dr Turner attempted to deploy on costs was the notion that none of the construction arguments impacted on other aspects of the case, obviousness in particular. The foundation for this argument, as I understood it, was the quote from Sandoz’s Opening Skeleton (which I cited at [259] of my judgment) where they stated a belief that there was common ground that the index value of 1.5 in the claim would

be understood to represent the dividing line between high and low risk of PML using the Gen2 assay of the patent – effectively Construction 6.

25. So the argument is that this was the construction on which Sandoz must have prepared its case. Furthermore, Biogen point out the shift in Sandoz’s argument on construction, from Construction 6 to Construction 5. Accordingly, Biogen say Sandoz did not run their inventive step case as a squeeze, Sandoz lost on obviousness and therefore Sandoz should be deprived of their costs relating to obviousness. In fact, Biogen’s argument appears to go further. As Ms French points out, the paragraph counting exercise related in Dr Gilbert’s evidence appears to attribute almost all of Professor Berger’s evidence to obviousness, so includes his analysis of the CGK, the prior art and EP792.
26. Sandoz’s response comprised the following points:
 - i) First, it was always clear that obviousness was being run as a squeeze – see the Amended Grounds of Invalidity, Sandoz’s opening skeleton argument and, above all, the Judgment.
 - ii) Ms French included a table at [21] of her second statement correctly identifying where my decision turned on the particular construction adopted.
 - iii) Accordingly, Sandoz had to run their spectrum of validity attacks to guard against the uncertainty as to what case Biogen would run on construction.
27. I agree. As for Biogen’s submission based on what was said in Sandoz’s opening skeleton on construction, it is clear to me that was a piece of advocacy designed to draw out what Biogen’s position on construction actually was. Notwithstanding that apparently confident statement, it was clear that Sandoz were continuing to run all their arguments to guard against where Biogen might go on construction.
28. Against this backdrop, I can turn to consider each of the 7 proposed heads of deduction.

Obviousness

29. At the outset it is clear that Biogen’s suggested deduction of 25% of Sandoz’s costs would be far too great, and Dr Gilbert’s paragraph counting exercise included aspects of the evidence on which I am clear that Sandoz should recover their costs as the successful party overall. However, when seeking to fix the appropriate deduction, there are a number of competing points which I must take into account.
30. First, the outcome of Sandoz’s obviousness attacks appears from my judgment. The attack based on WO369 failed on Construction 5, but only narrowly so, and would have succeeded on any of Constructions 1-3.
31. Second, it is clear that Sandoz needed to run the obviousness arguments in order properly to restrict Biogen as to what they could say on the insufficiency pleas.
32. Third, Sandoz’s obviousness arguments did not require much explanation over the disclosure of Gorelik and WO369. However, I also need to bear in mind how the obviousness arguments developed in the course of trial – the case run by Sandoz in closing was not the case advanced in their expert’s reports due to the issue of ‘access to samples’ which seemed to me to emerge only in the course of the trial.

33. Fourth, the explanation of Gorelik and WO369 were part of a narrative which led into and explained some of the teaching in EP792, not least because all three described the work of Biogen, albeit at different stages. In other words, most of the explanation of Gorelik and WO369 would have been required irrespective of whether Sandoz ran an obviousness attack. Indeed, as I pointed out at [345] of my Judgment, Biogen relied on Gorelik and/or WO369 as sources of information for the Gen1 assay in response to the allegations of classical and uncertainty insufficiency. Furthermore, it is clear that Sandoz should recover any costs attributable to the CGK.
34. With these points in mind as well as my overall impression of the significance of the obviousness arguments, I have concluded that the appropriate deduction from Sandoz's costs is 10%.

Technical Infringement

35. Looking at infringement generally, Biogen contended that Sandoz were only successful on the narrow issue of whether acts are performed outside the jurisdiction, a point limited to legal argument and not addressed in the expert evidence. As Sandoz pointed out, Biogen were conveniently forgetting that Sandoz succeeded on infringement on Constructions 1-3, and my conclusions on Construction 5 were closely tied up with my findings on insufficiency and construction. Furthermore, Sandoz did not contest equivalence in relation to the control composition feature on Actavis 1 and 2, but only on Actavis 3, so the main issues on technical infringement revolved around the 1.5 figure in the claim. Overall, even if I had decided against Sandoz on the territorial issue, Sandoz still would not have infringed because EP792 was invalid.
36. Biogen suggested that a 6% deduction should be made, but Sandoz said the paragraph counting was exaggerated and if any deduction were to be made, it should be limited to 2%.
37. In the unusual circumstances of this case, I do not consider that the aspects of technical infringement on which Sandoz lost amount to a suitably circumscribed issue. I make no deduction under this head.

Declaratory relief

38. Although there some factual evidence which went to this point, my impression was that the cross-examination of fact witnesses did not advance matters. The remaining time spent on this point was legal argument. For those brief reasons I will make the deduction proposed by Sandoz of 2% and not Biogen's suggestion of 3%.

Excluded Subject Matter

39. On this ground of invalidity, Sandoz failed on Construction 5 but would have succeeded on any of Constructions 1-3. Biogen suggested a deduction of 1%. Sandoz resisted any deduction, but if any deduction was to be made, they suggested it should be no more than 0.5%.
40. My conclusion is that no deduction should be made, because this was part of Sandoz's squeeze arguments to deal with the various constructions which appeared to being run by Biogen.

Sandoz's third counsel

41. Biogen ran a rather old-fashioned argument that the costs of Sandoz's third counsel should be deducted. Although Biogen were represented by two counsel, Sandoz pointed out that Biogen had not revealed the split in costs between their counsel and solicitors, so as to allow a comparison between the total counsel costs incurred on each side.
42. Biogen were not able to point out any respect in which the costs of Sandoz's third counsel were in any way excessive or that Sandoz's overall counsel costs were excessive. Furthermore, in cases of this complexity, it can often be more efficient to have a second junior employed at economical rates to conduct some of the work required for trials of this nature.
43. For all these reasons I see no basis for deducting the costs of Sandoz's third counsel.

US lawyers' fees

44. These fees were incurred because Dr Andersen and Dr Dugan were to give their evidence from the US by remote link and US lawyers were engaged to assist in the two different locations involved. Dr Andersen was cross-examined, albeit for a relatively short time. Sandoz withdrew Dr Dugan's evidence the night before she was due to be cross-examined. The total US lawyers' fees are some £12k. Ms French says the majority of those fees relate to the cross-examination of Dr Andersen. Bearing in mind he was only cross-examined for a short time, Dr Gilbert is of the view that the level of fees for facilitating the cross-examination of Dr Andersen was surprisingly high. Sandoz offer a deduction of 0.2% or some £3.5k, which are said to be the costs of the associate involved in arranging Dr Dugan's evidence, whereas Biogen suggest a deduction of £8k odd. The fact that Dr Dugan's evidence was withdrawn the night before will have saved some of these fees. In all the circumstances, I consider the appropriate deduction is £5k.

Dr Dugan

45. Finally, but by no means least, I must deal with the costs of Dr Dugan's evidence. Biogen say that Sandoz should not recover any of their costs of Dr Dugan's evidence and they should pay Biogen's costs of dealing with it. Biogen suggest that some £85,549 should be deducted from Sandoz's costs, a figure which is made up of Dr Gilbert's estimate of Sandoz's costs of preparing Dr Dugan's evidence (based on the proportion of paragraphs in Dr Dugan's evidence compared with the overall number of paragraphs in Sandoz's expert evidence), approximately £56k plus her estimate of Biogen's costs of dealing with Dr Dugan's evidence of £13k, plus Dr Dugan's own fees.
46. It is clear to me that Biogen's suggested deduction would be too great. First, the virological evidence was sequential, with Dr Dugan going first, with Professor Roy responding, primarily on HPVLPs. The bulk of Dr Dugan's 21-pages of her report related to CGK matters, indeed a number of paragraphs of her report were adopted as part of the Statement of Agreed CGK and Professor Berger said that [25]-[46] of her report were CGK and he was not challenged on that.

47. On the contentious topic of HPVLPs, 4 paragraphs of Dr Dugan's report, [70]-[73] were put to Professor Roy and she agreed with them. Those paragraphs comprise the bulk of Dr Dugan's section on HPVLPs, and are also paragraphs which Dr Dugan said were CGK.
48. Thus I have the impression that the bulk of Dr Dugan's report was accepted. Indeed, having reviewed her report, it strikes me that the remaining paragraphs were either introductory (instructions, Skilled Person) or which linked topics together. Accordingly, I agree with Sandoz's submission that Dr Dugan's evidence did the job which Sandoz required.
49. It was clear at the trial that Biogen were dismayed at the lack of opportunity to cross-examine Dr Dugan, so much was sought to be made about Sandoz's decision not to call Dr Dugan. Having analysed what happened to her evidence, for the purposes of these costs arguments, this was overblown.
50. Sandoz submitted that if there was to be any deduction at all, it should be on the basis of figures provided by Ms French, which were about half of Dr Gilbert's. She pointed out that on Biogen's approach, they deducted the costs of Dr Dugan's evidence twice – once under obviousness and separately when addressing the costs of her evidence directly. That point does not have the same force, in view of my decision on recovery in relation to obviousness, but I should still guard against double-deduction.
51. However, having considered Dr Dugan's evidence, I have concluded that any deduction involves far too much salami-slicing. Most of her evidence was accepted and the fact she was not called does not alter that. To the extent that any deduction is warranted, I have already made it under obviousness. So I make no additional deduction under this head.

Overall

52. Standing back, my analysis above suggests an overall deduction from Sandoz's costs of 12% + £5k, or about 12.3%. By coincidence this is the deduction in Sandoz's response column above. A deduction of greater than 15% would not, in my view, reflect the degree of success which Sandoz achieved on the complex web of issues in this case, so the deduction of 12.3% feels correct. Accordingly, my costs order will be that Biogen are to pay 87.7% of Sandoz's costs. This percentage figure is to be applied to the totality of Sandoz's costs, including the post-trial costs which were not included in the table above.

Interim Payment

53. The parties agreed that the Interim Payment should be calculated at 70% of the estimated costs award, so I ask the parties to agree the appropriate sum.

CONFIDENTIALITY

54. The trial bundles contained documents designated Confidential and Highly Confidential to Sandoz, relating to the alleged infringement. In the usual way, I made Orders *pro tem* under CPR31.22 and 32.13 to preserve confidence. Sandoz now seek

final Orders under those provisions but in respect of a reduced set of documents and information.

55. Through Dr Gilbert, Biogen take a neutral stance regarding confidentiality, leaving it to Sandoz to persuade the Court where confidentiality should be maintained.
56. Now that Sandoz's Tyruko product and the ImmunoWELL testing service have been launched, Sandoz accept that 6 documents are no longer confidential (as listed by Ms French in her evidence).
57. Ms French also exhibits a detailed table which identifies all the documents or parts in which Sandoz seek to retain confidence. It is clear from this that Sandoz do not make blanket assertions of confidence but have explained and justified their application.
58. Ms French and her exhibited table also draw attention to documents which contained certain pieces of information which were confidential when the documents were prepared (e.g. the Skeleton Arguments) but no longer. I agree that it would be disproportionate to require Sandoz to prepare new copies of those documents, reflecting the current status of the information. It may be that such documents will have to be prepared for use in any appeal from my judgment, but I do not propose to anticipate that.
59. For these brief reasons, I approve Sandoz's position as to the documents and information over which I should make final CPR31.22 and 32.13 orders.
60. I ask Counsel to agree an Order giving effect to this judgment.