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Case No: CL-2022-000278

IN THE HIGH COURT OF JUSTICE
BUSINESS AND PROPERTY COURTS OF ENGLAND AND WALES
KINGS BENCH DIVISION
COMMERCIAL COURT

Royal Courts of Justice, Rolls Building
Fetter Lane, London, EC4A 1NL

Date: 21/04/2023

Before :

DAME CLARE MOULDER DBE
sitting as a Judge of the High court

- -

Between :

CIPLA LIMITED	**Claimant**
- and -	
SALIX PHARMACEUTICALS, INC.	**Defendant**

- -
- -

Nicholas Saunders KC and Tom Foxton (instructed by **K&L Gates LLP**) for the **Claimant**
Andrew Waugh KC, Siddharth Dhar and Katherine Moggridge (instructed by **McDermott Will & Emery LLP**) for the **Defendant**

Hearing dates: 21 March 2023

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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.

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Dame Clare Moulder DBE :

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Introduction

1. The Claimant in these proceedings (and the Claimant in the arbitral proceedings under appeal), Cipla Limited ("Cipla"), applies under section 68 of the Arbitration Act 1996 (the "1996 Act") for an Order remitting a Partial Award on Outstanding Issues of Liability dated 3 May 2022 (the "Award") made by the Rt. Hon. Lord Neuberger of Abbotsbury (the "Tribunal") in an arbitration conducted under the LCIA Rules 2014 on the ground of a failure by the Tribunal to comply with its duty under section 33 of the 1996 Act, which constitutes a "serious irregularity" affecting the Award under section 68(2)(a) of the 1996 Act.

Background

2. The dispute between the parties arises out of an Exclusive License Agreement dated 1 October 2009 (the "2009 Agreement"). Under the 2009 Agreement, Cipla licenced the use of certain patent claims to Salix. These patent claims were in respect of a compound known as amorphous rifaximin. In exchange for the grant of the licences under the 2009 Agreement, Salix agreed to pay Cipla royalties on the sale of any Salix products that, absent the licences so granted, would infringe Cipla's amorphous rifaximin patents.

3. Since 2004, Salix has manufactured a drug product sold under the brand name XIFAXAN®, which is an antibiotic used to treat various conditions including diarrhoea and irritable bowel syndrome. Prior to the Award, Salix has always maintained that XIFAXAN® contains only crystalline rifaximin (and no amorphous rifaximin). Cipla brought the arbitration on the basis that XIFAXAN® tablets in fact contain amorphous rifaximin and that, accordingly, sales of XIFAXAN® tablets fall within the scope of the 2009 Agreement.

4. The central issue in the arbitration was whether Salix was obliged under the 2009 Agreement to pay Cipla a royalty on sales of its XIFAXAN® tablets. The 2009

Agreement provided that a royalty was due to Salix on sales of any "Licensed Product" which was defined as "*any product […] the manufacture, use, sale […] of which would, absent the license granted to Salix hereunder, infringe any Valid Claim included in the Licensed Patent Rights*". Cipla's case was, in essence, that Cipla had five Valid Claims to amorphous rifaximin. Two of the claims were valid because they were made in granted/issued patents ("Claims (b) and (c)" or the "Issued Claims"). The remaining three claims ("Claims (a), (d) and (e)" or the "Pending Claims") were Valid Claims because they had been diligently prosecuted.

5. Salix's case was that only the Issued Claims were Valid Claims (the Pending Claims were not Valid Claims because they had not been diligently prosecuted); XIFAXAN® tablets did not contain amorphous rifaximin (only crystalline rifaximin); even if XIFAXAN® tablets did contain amorphous rifaximin, XIFAXAN® tablets (i) do not infringe any claims, because all claims required the tablets to be essentially free of crystalline rifaximin, and the tablets contain at least some crystalline rifaximin (whether or not they also contain amorphous rifaximin); and (ii) XIFAXAN® tablets do not infringe the Issued Claims because the amorphous rifaximin in XIFAXAN® tablets had not been shown by Cipla to produce the Figure 1 XRPD Pattern; Cipla was estopped by convention from contending that XIFAXAN® tablets contained amorphous rifaximin.

6. The Tribunal agreed with Salix that the Pending Claims had not been diligently prosecuted and so were not valid (Award, paras 71-99). Cipla does not seek to challenge that conclusion. That meant that Cipla had to show that XIFAXAN® tablets infringed one of the two Issued Claims.

7. The next question was whether XIFAXAN® tablets would, absent the licence conferred by the 2009 Agreement, infringe the Issued Claims. That in turn raised two issues: (i) the proper construction of the Issued Claims as a matter of US law (i.e. what needed to be shown to prove infringement); and (ii) whether XIFAXAN® tablets contained amorphous rifaximin (as Cipla contended) such that the tablets are covered by the Issued Claims.

8. Dr Kaduk, Cipla's expert carried out XRPD (x-ray powder diffraction) analysis, a technique that reveals structural information about compounds. XRPD analysis can determine the solid form of a material and can also distinguish among polymorphs of the same material. For example, it can distinguish between crystalline materials and amorphous materials. Unlike crystalline rifaximin the XRPD of amorphous rifaximin does not demonstrate distinct peaks but exhibit a "halo".

9. The Tribunal agreed with Salix, holding that the words "*characterized by the XRPD pattern shown in FIG. 1*" in the Issued Claims limited the ambit of the claim to amorphous rifaximin which, upon being subject to XRPD, produced a Figure 1 XRPD Pattern (Award, para 139).

10. The Tribunal held that there was no evidence that the amorphous rifaximin present in XIFAXAN® tablets produced the Figure 1 XRPD Pattern (Award, para 151) with the result that, even though Cipla succeeded in showing that XIFAXAN® tablets contained amorphous rifaximin, it could not show that the XIFAXAN® tablets contained the amorphous rifaximin covered by the Issued Claims.

11. The Tribunal then went on to consider whether XIFAXAN® tablets contain amorphous rifaximin. The Tribunal concluded that, on the balance of probabilities, XIFAXAN® tablets did contain appreciable amounts of amorphous rifaximin (Award, para 279).

12. The Tribunal also rejected the estoppel argument (Award, para 284 - para 292).

Chronology

13. So far as material to the issues before this Court, the chronology of the arbitration proceedings was as follows:

14. The Tribunal was appointed on 15 April 2020.

15. Cipla served its Statement of Case on 5 August 2020.

16. On 27 January 2021, Salix served its Statement of Defence. In its Defence Salix pleaded that:

> "*207. Salix's primary position is that XIFAXAN® tablets are not Licensed Products because the Valid Claims would only be infringed if XIFAXAN® tablets were "essentially free of crystalline rifaximin" and/or were "characterized by the XRPD pattern shown in Figure 1" of the common specification…*
>
> *…*
>
> *209. As to the latter, the tablets are not "characterized by the XRPD pattern shown in Figure 1" even on Dr. Kaduk's alleged evidence. Dr. Kaduk's XRPD diffractograms of XIFAXAN® tablets do not have the characteristic pattern of amorphous material shown in Figure 1. XIFAXAN® tablets would have to have the XRPD pattern shown in Figure 1 for Cipla to prove infringement of claims with the "Figure 1" limitation, and they do not.*" [emphasis added]

17. Cipla served its Statement of Reply on 25 August 2021.

18. Salix served its Rejoinder on 6 October 2021. At paragraph 136 Salix pleaded:

> "*Cipla has failed to meet its burden of proving infringement of these claims because it does not have even a single XRPD diffractogram of XIFAXAN® tablets or its API that has the halo pattern of Figure 1. Proof of infringement requires proof that the accused product meets each and every claim element. Proof of "rifaximin in an amorphous form characterized by the XRPD pattern of FIG.1" requires the accuser to provide an XRPD of the accused product that has the pattern of FIG. 1. Cipla has failed to do so.*"

19. The merits hearing was held between 25 October 2021 and 30 October 2021, in advance of which each party submitted an opening skeleton argument.

20. On 6 January 2022, Cipla and Salix each submitted written closing submissions.

21. On 31 January 2022 and 1 February 2022, the Tribunal heard oral argument on the written closing submissions.

The Award

22. On 3 May 2022, the Tribunal signed and dated the Award. The Award dismissed Cipla's claim for a royalty for sales of XIFAXAN® tablets under the 2009 Agreement.

23. At paragraph 139 of the Award the Tribunal held that:

> "*I am of the view that the XRPD Claims only extend to products which contain amorphous rifaximin which produces a FIG 1 XRPD pattern (and, I should add for the avoidance of doubt that, if such a product also contains other rifaximin, whether amorphous or not, it would still infringe the XRPD Claims).*"

24. The Tribunal concluded at paragraph 140 ii that:

> "*The Patent Claims, Claims (b) and (c), are each Valid Claims, but they only extend to products which include amorphous rifaximin which produces a FIG 1 XRPD pattern.*"

The Tribunal held in this regard:

> "*142. As to the second of the conclusions in paragraph 140 above, it means that Cipla can only succeed in establishing that XIFAXAN® tablets would be Licensed Product by virtue of the Patent Claims if it could establish that they contain amorphous rifaximin which produces a FIG 1 XRPD pattern. In other words, it is not enough for Cipla to establish that XIFAXAN® tablets contain amorphous rifaximin on the fourth issue: at least some of that amorphous rifaximin must produce a FIG 1 XRPD pattern.*
>
> *143. This gives rise to the third issue: Salix contended that, even if, contrary to its contention, Cipla is successful on the fourth issue, and I am persuaded by Dr Kaduk's evidence that XIFAXAN® tablets contain amorphous rifaximin, Cipla would still fail to establish that XIFAXAN® tablets were Licensed Product because no evidence has been adduced to show that any of that amorphous rifaximin has a FIG 1 XRPD pattern, although each of the Parties tried to introduce such evidence.*
>
> *144. In the set of slides used in her presentation, Dr Linck included a slide which suggested that any amorphous rifaximin will inherently have a FIG 1 XRPD pattern. However, this had not been asserted in any of Cipla's written evidence or submissions, and, when that point was made, the slide was withdrawn. In closing, Cipla argued that, in various passages, Salix's pleaded case and Judge Rader's declarations effectively accepted, or even contended, that amorphous rifaximin always produced an XRPD as shown in FIG 1. However, I consider that it is clear that the passages relied on were directed to the amorphous rifaximin as claimed in the relevant patents, and not to amorphous rifaximin generally. Thus, one of the passages relied on stated that "the characteristic shape of the XRPD pattern shown in Figure 1 pattern was an inherent property of the claimed amorphous rifaximin."*
>
> *145. Salix also sought to put in late evidence, which suggested that amorphous rifaximin could produce different XRPDs, and that not all amorphous rifaximin produced a FIG 1 XRPD. I acceded to Cipla's submission that this evidence was presented too late to be admitted, and accordingly it was excluded. In the course*

of his cross-examination, however, after referring to the fact that "the amorphous comes out as broad double halo", i.e. the FIG 1 XRPD, Dr Swaminathan said that "there is more than one amorphous, it could come out as a different halo".

146. When it comes to the question whether the amorphous rifaximin in the XIFAXAN® tablets infringes the XRPD Claims, the onus is on Cipla to prove infringement, not on Salix to prove no infringement. It therefore appears to me to follow as a matter of principle that, in the light of the way in which I have concluded the XRPD Claims should be interpreted, it is up to Cipla to prove that, assuming that XIFAXAN® tablets contain amorphous rifaximin, at least some of that amorphous rifaximin has a FIG1 XRPD pattern. And Salix's simple point was that, even assuming that Dr Kaduk's evidence persuades me that XIFAXAN® tablets contain amorphous rifaximin, there is simply no evidence that any of that amorphous rifaximin has a FIG 1 XRPD pattern.

…

150. It therefore appears to me that, unless it can be said to be up to Salix to show that amorphous rifaximin does not always produce a FIG 1 XRPD, or unless there is some reason for thinking that that is the case, Cipla's case that the XIFAXAN® tablets infringe the XRPD Claims must fail, because, even if those tablets contain amorphous rifaximin, Cipla has not established that any of that rifaximin has a FIG 1 XRPD. And in my view, there is no basis for saying that it is up to Salix to show that amorphous rifaximin does not always produce a FIG 1 XRPD. On a fair view of the evidence, there is no evidence to suggest even faintly that the FIG 1 XRPD is always thrown up by amorphous rifaximin. In so far as there is any evidence, it points the other way, namely in Dr Swaminathan's somewhat throw-away line in cross-examination, but in my opinion that is an insufficiently clear or tested piece of evidence on which to base any conclusion.

151. The essential point is that, given that there is no evidence which suggests that all amorphous rifaximin has a FIG 1 XRPD, one is thrown back on the proposition that, in order to establish infringement of a claim, a patentee must establish, albeit only on the balance of probabilities, that each aspect of a product claim is infringed by the allegedly infringing article, and therefore, even if XIFAXAN® tablets contain amorphous rifaximin, Cipla has failed to establish that they infringe the XRPD Claims.

152. It might appear a little surprising to a notional outside observer of the six-day hearing that Cipla's claim to recover what appears likely to be a very substantial sum of money is defeated by what may be characterised as a rather short and technical point, particularly given that relatively little time was spent in argument and even less time was spent in evidence on the point. However, that is not a reason for rejecting Salix's case on the point, if, as I have concluded, it is a good case…". [emphasis added]

Relevant law

25. Section 68 of the 1996 Act provides (so far as relevant):

"*(1) A party to arbitral proceedings may (upon notice to the other parties and to the tribunal) apply to the court challenging an award in the proceedings on the ground of serious irregularity affecting the tribunal, the proceedings or the award.*

A party may lose the right to object (see section 73) and the right to apply is subject to the restrictions in section 70(2) and (3).

(2) Serious irregularity means an irregularity of one or more of the following kinds which the court considers has caused or will cause substantial injustice to the applicant—

(a) failure by the tribunal to comply with section 33 (general duty of tribunal);

(b)..."

26. Section 33 of the 1996 Act provides:

"*(1) The tribunal shall—*

(a) act fairly and impartially as between the parties, giving each party a reasonable opportunity of putting his case and dealing with that of his opponent, and

(b) adopt procedures suitable to the circumstances of the particular case, avoiding unnecessary delay or expense, so as to provide a fair means for the resolution of the matters falling to be determined.

(2) The tribunal shall comply with that general duty in conducting the arbitral proceedings, in its decisions on matters of procedure and evidence and in the exercise of all other powers conferred on it."

27. The application of the law in this area was largely common ground. The duty under section 33 is summarised in *Russell on Arbitration* (24th ed) as follows:

"*To comply with its duty to act fairly under s.33(1) of the Arbitration Act 1996, the tribunal should give the parties an opportunity to deal with any issue which will be relied on by it as the basis for its findings. The parties are entitled to assume that the tribunal will base its decision solely on the evidence and argument presented by them prior to the making of the award. If the tribunal is minded to decide the dispute on some other basis, the tribunal must give notice of it to the parties to enable them to address the point. Particular care is needed where the arbitration is proceeding on a documents-only basis or where the opportunity for oral submissions is limited. That said, a tribunal does not have to refer back to the parties its analysis or findings based on the evidence or argument before it, so long as the parties have had an opportunity to address all the "essential building blocks" in the tribunal's conclusion. Indeed, the tribunal is entitled to derive an alternative case from the parties' submissions as the basis for its award, so long as an opportunity is given to address the essential issues which led the tribunal to those conclusions.*"

28. Cipla relied on a number of authorities which it said supported its case:

(1) *Interbulk Ltd v Aidan Shipping Co Ltd ("The Vimeira")* [1984] 2 Lloyd's Rep 60 where an award was remitted because the tribunal decided the arbitration on the basis of a point which was never raised as an issue or argued before the arbitrators;

(2) *Cameroon Airlines v Transnet Ltd* [2004] EWHC 1829 (Comm), where the tribunal determined the restitutionary sum on a basis not contended by either party;

(3) *OAO Northern Shipping Co v Remol Cadores De Marin SL* [2007] EWHC 1821 where the tribunal decided an issue where there had been no argument or discussion directed towards the issue;

(4) *Ducat Maritime Ltd v Lavender Shipmanagement* [2022] EWHC 766 where Butcher J held that the irregularity was that an arbitrator had failed to adhere to the common ground between the parties, in deciding how much was owed on a basis which had not been argued by either party, without giving them the opportunity to comment on it;

(5) *Royal & Sun Alliance Insurance Ltd v Tughans (A Firm) [2022]* EWHC 2589 (Comm), in which Foxton J found that a serious irregularity had occurred in circumstances where an issue had not formed part of one party's case, the merits hearing proceeded on that basis, but the point was nonetheless raised in the party's closing submission.

29. I do not propose to consider the facts of these cases in detail as the claim before this Court turns in my view on the analysis of the facts of what occurred in this case and the application of the legal principles to the specific facts. However it is helpful to set out the following exposition of the law from the judgment of Gloster J in *OAO Northern Shipping* at [21]-[23]:

> "*21. Thus, Ackner LJ in The Vimeira [1984] 2 Lloyd's Rep 66 at page 76 stated:*
>
> > *The essential function of an arbitrator . . . is to resolve the issues raised by the parties. The pleadings record what those issues are thought to be and, at the conclusion of the evidence, it should be apparent what issues still remain live issues. If an arbitrator considers that the parties or their experts have missed the real point... then it is not only a matter of obvious prudence, but the arbitrator is obliged, in common fairness or, as it is sometimes described, as a matter of natural justice, to put the point to them so that they have an opportunity of dealing with it...*
> >
> > *. . . the adequacy of the turning area was not at the conclusion of the evidence — even though it was a possible issue at the commencement of the arbitration — any longer a live issue. The arbitrators clearly thought otherwise. They should have so informed the parties...*
>
> *and (per Bingham LJ) in Zermalt Holdings SA v Nu Life Upholstery Repairs Ltd [1985] 2 EGLR 14 at page 15:*

> *If an arbitrator is impressed by a point that has never been raised by either side then it is his duty to put it to them so that they have an opportunity to comment. If he feels that the proper approach is one that has not been explored or advanced in evidence or submission, then again it is his duty to give the parties a chance to comment. If he is to any extent relying on his own personal experience in a specific way, then that again is something that he should mention so that it can be explored. It is not right that his decision should be based on specific matters which the parties never had the chance to deal with, nor is it right that a party should first learn of adverse points in a decision against him. That is contrary both to the substance of justice and to its appearance...*
>
> *22. These principles apply to unargued points of law or construction as they do to unargued questions of fact. In such cases, whilst it is not necessary for the tribunal to refer back to the parties each and every legal inference which it intends to draw from the primary facts on the issues placed before it, the tribunal must give the parties ''a fair opportunity to address its arguments on all of the essential building blocks in the tribunal's conclusion'' (ABB AG v Hochtief Airport GmbH [2006] 2 Lloyd's Rep 1 at para 70).*
>
> *23. Here, the ''representation'' issue was one of the ''essential building blocks'' of the tribunal's decision. Counsel for buyers had proceeded on the assumption that the point was no longer in issue (if it ever had been), and therefore did not need to be addressed. As Mr Wilson has stated, the tribunal did not invite submissions on the representation issue. This was not simply a case of a tribunal drawing a further inference on an issue which the parties had otherwise had the opportunity to address. Indeed, it is perhaps surprising that the tribunal received written submissions after the hearing as to which of the GL certificate and GA plan were relied upon (if either), but again did not invite submissions on its intended 'no representation' point*". [emphasis added]

30. Cipla placed reliance on *Sun Alliance* for the proposition that the opportunity to serve submissions did not adequately address the issue of unfairness where a party has conducted its case on the basis that an issue is no longer live and submitted that it highlights that the injustice is in how the case is conducted rather than how it is pleaded. At [86] of the judgment Foxton J identified the serious irregularity in that case:

> "*I have reluctantly come to the conclusion that the Arbitrator's decision to grant the Disputed Declarations in circumstances in which:*
>
> *i) Tughans had expressly disclaimed any application for relief in respect of the Tughans Fee Damages Claim save on the basis of the Qualified Claim;*
>
> *ii) the merits hearing had been conducted by both parties on that basis; and*
>
> *iii) RSA had made it clear in its Defence and Counterclaim that there were alternative arguments it reserved the right to put forward had the point been advanced;*

> *involved a serious irregularity. The decision involved a failure to allow RSA a reasonable opportunity to present its case and/or deal with Tughans' case as newly formulated for the purposes of s.33(1)(a) and s.68(2)(a) of the 1996 Act and a failure to conduct the proceedings in accordance with the procedure agreed by the parties (namely by reference to the matters in issue as defined in the statements of case and submissions served before the merits hearing).*"

31. I note the particular facts of that case were that there had been an express disclaimer and the hearing had been conducted on that basis. Accordingly I gain no real assistance on the facts of this case.

32. Finally I remind myself of the "*high hurdle*" that Cipla has to surmount on an application to challenge an arbitration award under section 68. As Butcher J set out in *Ducat Maritime* at [23]:

> "*There can also be no dispute that an applicant, under section 68, has to surmount a "high hurdle", as it was put in Bandwidth Shipping Corporation v Intaari (The 'Magdalena Oldendorff') [2007] 2 CLC 537 at [35], or "high threshold" as it was put in Lesotho Highlands Development Authority v Impregilo SpA and Others [2006] AC 221 at [28] and bears a "heavy burden", as was said in New Age Alzarooni 2 Ltd and Another v Range Energy Natural Resources Inc [2014] EWHC 4358 (Comm) at [12]. As was explained in paragraph 280 of the DAC report on the Arbitration Bill which led to the Arbitration Act 1996, the section was "really designed as a long stop, only available in extreme cases, where the tribunal has gone so wrong in its conduct of the arbitration that justice calls out for it to be corrected"*."

The arbitration claim

33. In the Arbitration Claim Form the grounds which were said to constitute the serious irregularity related to the Tribunal's conclusions in paragraphs 146, 150 and 151 of the Award. In those paragraphs, the Tribunal concluded that Cipla had failed to discharge its burden of showing that the amorphous rifaximin found to be present in Salix's XIFAXAN® tablets produces the Figure 1 XRPD pattern. The Tribunal concluded at paragraph 150 of the Award that there was "*no evidence to suggest even faintly that the Figure 1 XRPD is always thrown up by amorphous rifaximin*". Cipla's case as set out in the Arbitration Claim Form was that that finding overlooked the accepted evidence of Salix's own expert on that issue.

34. By its skeleton for this hearing that ground appeared to have been largely abandoned (though I deal with it below) and the oral submissions to the Court for Cipla were on the basis that by a ruling on 26 October 2021 (the "26 October ruling") by which the Tribunal excluded certain evidence that Salix had sought to introduce late in the proceedings, the Tribunal had ruled that the issue of whether XIFAXAN produced the Figure 1 XRPD pattern was not an issue between the parties. Accordingly it was submitted that it was unfair for the Tribunal to conclude in the Award that Cipla had failed to discharge the burden of showing that the amorphous rifaximin in the tablets produced the Figure 1 XRPD pattern. It was submitted for Cipla (paragraph 16 of its skeleton) that there was a "*fundamental incompatibility*" between the 26 October ruling and the Tribunal's subsequent approach to and conclusions on that issue in the Award.

35. The alleged serious irregularity raised by this appeal thus concerns the Tribunal's approach to the Figure 1 Issue.

The 26 October Ruling

Context of the 26 October ruling

36. It is important to consider the context of the 26 October ruling which was given by the Tribunal on Day 2 of the merits hearing.

37. The first thing to note is that in oral openings the issue of whether there might be multiple forms of amorphous rifaximin that could produce XRPD patterns other than the FIG 1 XRPD Pattern was raised by way of a question from the Tribunal. Initially counsel for Salix indicated that there could not be. But counsel subsequently corrected this statement later in oral openings as follows.

> "*MR. WAUGH: You asked me specifically a question, "If all amorphous rifaximin has the XRPD of Figure 1". I may have misled you, but the answer is "No". I am told there are different amorphous forms. It is called polyamorphism.*
>
> *THE ARBITRATOR: Right.*
>
> *MR. WAUGH: Each has a different XRPD. What that means is that Figure 1 is not the inherent feature of all amorphous rifaximin. Figure 1 is a limitation to this particular form of amorphous rifaximin made by this patent. Figure 1 is the fingerprint or hallmark of rifaximin made by this patent if you follow the procedure, but not of all amorphous rifaximin."* [emphasis added]…
>
> *THE ARBITRATOR: Right. It is only one type of amorphous rifaximin, then, that you say is covered by this patent?*
>
> *MR. WAUGH: Yes*" [emphasis added]

38. After the exchange Mr Saunders for Cipla interjected there was nothing in evidence about polyamorphism. The Tribunal noted the objection responding as follows:

> "*It is a fair point Mr. Saunders, subject to being taken to some evidence, but as Mr. Waugh says, he was answering my question*".

39. The following day Cipla then sought to introduce evidence on the point by a slide from a witness Dr Linck which stated that:

> "*The XRPD pattern for amorphous rifaximin is an inherent property of amorphous Rifaximin, i.e., it necessarily has such a pattern.*
>
> *Thus, once the presence of amorphous rifaximin has been established, no additional evidence is necessary to establish that claim forms (b), (c), and (e) are also infringed*". [emphasis added]

40. Dr Linck also stated in her oral evidence that the phrase characterised by the XRPD pattern showing in Figure 1 was not an additional limitation because her understanding

was that the XRPD pattern was inherent in the amorphous rifaximin so it was not necessary for Cipla to prove that that pattern was present.

41. As a result Salix informed Cipla that it was intending to put documents to Dr Kaduk in response to the evidence of Dr Linck that the XRPD pattern was an inherent property of amorphous Rifaximin.

42. Cipla objected and the issue of whether these documents could be put to Dr Kaduk was then raised before the Tribunal.

43. Salix objected that this was the first time that Cipla had advanced a case that this is an inherent property of amorphous rifaximin.

44. Cipla submitted that polyamorphism was a totally new point that was being advanced for the first time by Salix and it would be unfair to put it to Dr Kaduk.

45. Mr Saunders KC for Cipla submitted that it was common ground between Dr Rader and Dr Linck that the "halo" shape is an inherent property of the amorphous rifaximin of their invention. He further submitted that everybody was agreed there was one pattern for amorphous rifaximin and Cipla's testing protocols were based on that approach. He submitted that the way the testing worked was that it looked for amorphous rifaximin by stripping out everything else and that if the case was being run that there were multiple different forms of amorphous rifaximin, that would have impacted the testing protocols that were sorted out almost a year before the hearing. [p254 of Day 2 transcript] It was submitted for Cipla that it was inconsistent and unfair. Mr Saunders relied on passages from the evidence of Dr Myerson and Dr McClurg, Salix's witnesses.

46. Salix responded to these submissions denying that the evidence of Dr Myerson and Dr McClurg established the inherency point.

47. Mr Saunders then indicated that Cipla was content to withdraw the slide in issue and the answers in connection with it. However Mr Waugh continued to press to allow the documents to be put to Dr Kaduk.

48. Having heard the parties in connection with Cipla's objection, the Tribunal adjourned the hearing for a short time to consider its ruling and then gave a short judgment in which it agreed with Cipla and excluded the late evidence.

The substantive ruling

49. The substantive part of the ruling needs to be considered in its entirety given the significance which Cipla attach to the ruling before this Court:

> "*…I have to consider what may either be called an application to put in some new evidence or an objection to the putting in of new evidence and, indeed, the putting of certain documents to a witness.*
>
> *I am not going to set out the background, but basically, the point is that this evidence may – I have not seen it – may call into question an assumption which is said to have been made that amorphous rifaximin produces one XRPD pattern*

and, if that assumption is wrong then it may call into question the conclusions reached by the witness concerned, Dr. Kaduk, in his evidence.

The objection to this evidence being put, or these documents, as I will call them, being put is that nowhere in the respondent's case has that point, namely, that amorphous rifaximin may have more than one XRPD pattern, been raised as a reason for doubting Dr. Kaduk's conclusion and it would operate as, effectively, an ambush on the claimant's case and, on his evidence, and wholly contrary to the cards-on-the-table approach.

The answer that is given is that it arises from a question I put yesterday on the first day of the hearing, namely, whether there was more than one XRPD pattern for amorphous rifaximin and/or from evidence given by the first, and so far only, witness in this case, Dr. Linck, on slide 29 of her set of slides. In addition, the respondents rely on paragraph 18 of the ruling I gave on 2nd October.

The natural instinct of any judge or arbitrator is to allow in evidence if it can possibly be justified on the basis that: (a) the evidence can be ignored in due course, unlike with a jury trial, if the tribunal considers it appropriate; and (b) in any event, it is better to have a decision based on all available information rather than keeping information out.

But, in this case, I have reached the conclusion that it would be wrong to allow this evidence in. It seems to me that to base it on a question I raised cannot be right, because the proper answer to the question is it does not arise. So far as Dr. Linck's evidence is concerned, the evidence has been withdrawn and, in any event, it is right to record that I read it as not expressing a view from someone who had no basis or expertise for the view that there was only one XRPD pattern for the amorphous rifaximin, but merely that that was what the patent provided, because she was put forward as an expert on how a patent would be read. So far as the evidence is concerned, the respondent has had a full opportunity to comment on Dr. Kaduk's evidence and has produced, I think, well over 350 pages of expert evidence relating to Dr. Kaduk's evidence and in the form of four witness statements, at least, dealing with that in some detail and has not raised this point. In addition, it does seem to me that passages in some of the evidence suggests that there is only one XRPD pattern for amorphous rifaximin. For instance, and perhaps most notably, Dr. Myerson says that "amorphous rifaximin is known to provide an XRPD signal. That pattern is provided in Figure 1 of Cipla's own patent". There is no suggestion there is any other pattern or signal that might be made…

In those circumstances, to raise a point which could have been raised at any time before and, if it was going to be raised, should have been raised in accordance with normal principles, and to raise it at this stage for the first time when Dr. Kaduk is about to be cross-examined, does seem to me to be unfair. The temptation to let it in at this stage and see what happens is considerable, but once it is out there, the danger is that the damage is done. It is one thing to say one will ignore a piece of evidence because it is unfair to do so, but it seems to me in relation to this evidence, there is a real risk that that would not be possible. Once it was out, it was out. Therefore, one has to make a decision now. Mr. Waugh, understandably, pressed paragraph 18 of my decision, as I have mentioned. That

> *has to be read, as Mr. Saunders said, in context. It is quite clear from paragraphs 4 and 5 that if a party wanted to push a whole new case or an important new argument which relied on evidence and so on, then they were meant to produce that evidence well in advance. Paragraph 18, which does deal with points to be put, is not concerned with wholly new points which have not been raised before, but has to be read together with paragraphs 4 and 5 and, it seems to me, it is concerned with matters such as, "You said something inconsistent in a previous case" and the like, but not something as fundamental as this. I take heart from the fact that it is not the case that the respondent relied on paragraph 18 and kept this up its sleeve, which would not be very attractive, but would give rise to a point of fairness in their favour. It is only a point which occurred to them as part of their case yesterday.*
>
> *With some regret but bearing in mind my duty is to ensure a fair hearing, I have concluded this evidence should not be put and should not be put in and should not be put to the witness*." [emphasis added]

What did the 26 October ruling decide?

Submissions

50. For Cipla it was submitted that the effect of the 26 October ruling was that the "issue" of whether amorphous rifaximin could produce more than one XRPD pattern was not live between the parties. More particularly it was submitted that by the 26 October ruling the Tribunal held that the argument that amorphous rifaximin might produce more than one XRPD pattern had never been raised (the polyamorphous argument) and on this basis the Tribunal excluded evidence going to that issue. It was submitted that the consequence of the 26 October ruling was that for the purpose of the arbitration:

    (i) The parties cases had been advanced that amorphous rifaximin necessarily exhibited the Fig 1 pattern;

    (ii) Any evidence to the contrary was expressly excluded;

    (iii) It was not open to Salix to argue that there could be more than one form of amorphous rifaximin (the polyamorphous argument) or that amorphous rifaximin might produce an XRPD pattern different from the Fig 1 pattern (the inherency argument).

51. Cipla's challenge before this Court (as advanced in its written skeleton and oral submissions) is that by finding in the Award that Cipla had failed to prove that the Fig 1 pattern was exhibited by the amorphous rifaximin found to be present in XIFAXAN, the Tribunal assumed that there might be more than one form of amorphous rifaximin and that it may not always produce the Fig 1 pattern and in the light of the 26 October ruling that amounted to a serious irregularity.

52. Cipla relied on the sentence by the Tribunal in the 26 October ruling that :

> "*the proper answer to the question is it does not arise.*"

53. It was submitted for Cipla that the 26 October ruling was a ruling on the ambit of the issues and the Tribunal ruled that the issue did not arise. It was therefore submitted for Cipla (para 42 of its skeleton) that by considering whether Cipla had discharged the burden of proof on this issue, the Tribunal decided the arbitration on a point that was not raised as an issue or argued.

54. It was further submitted for Cipla that (paragraphs 43.2 and 43.3 of its skeleton):

    (1) in light of the 26 October ruling Cipla was entitled to proceed on the assumption that the question of whether amorphous rifaximin might produce more than one XRPD pattern was no longer in issue.

    (2) In the 26 October ruling the Tribunal ruled that the suggestion that amorphous rifaximin might produce more than one XRPD pattern had not been properly raised by Salix and moreover that it was too late to raise it on Day 2 of the hearing. The merits hearing therefore proceeded on the basis that the point was not being run.

55. Cipla noted that the observation by the Tribunal at paragraph 152 of the Award that "*relatively little time was spent in argument and even less time was spent in evidence on the point*" was because the Tribunal had previously ruled in the 26 October ruling (i) that the suggestion that amorphous rifaximin might have multiple forms with different XRPD patterns had not been raised/was not in issue and (ii) all the evidence supported the proposition that the Fig 1 pattern was an inherent feature of amorphous rifaximin.

56. It was therefore submitted that this was a "paradigm case" of a serious irregularity arising from a breach by the Tribunal of its duty under section 33 of the Act to act fairly and impartially between the parties giving each party a reasonable opportunity of putting its case and dealing with that of his opponent.

57. For Salix it was submitted that:

    (1) the 26 October ruling was to the effect that it was unfair to put the questions to Dr Kaduk given that Dr Kaduk had led no evidence on point.

    (2) it was clear that throughout the arbitration the question of proof was always live; the 26 October ruling was not determinative on this point.

    (3) in oral closings Cipla sought to rely on the evidence of Judge Rader; Cipla did not submit that the arbitrator should look to the evidence of Professor Myerson, nor did it submit that the arbitrator had already ruled on that evidence.

    (4) Cipla should have raised the issue in closing submissions if it wanted to say that the arbitrator had already ruled on the issues and that it had therefore been deprived of an opportunity to put the case to witnesses. It was submitted that Cipla in its skeleton ignored the dialogue with the arbitrator and in particular the closing submissions.

    (5) the arbitrator dealt properly and fairly with the issues and did not overlook any evidence.

Closings

58. It is relevant to consider the closing submissions in the merits hearing to see whether the interpretation which Cipla now place on the 26 October ruling and which Cipla say affected the subsequent conduct of their case is borne out.

Written closings

59. In its written closing submissions Salix submitted as follows:

> "*106. It was Cipla's burden to prove inherency. But Cipla adduced no evidence that there is only one form of amorphous rifaximin or that any amorphous rifaximin will inherently have the XRPD pattern of FIG. 1. The unchallenged testimony of Dr. Swaminathan was that there is "more than one amorphous" rifaximin and that other amorphous forms would have a different halo pattern… It is not Salix's burden to prove non-inherency, but the only related evidence in the record nonetheless supports Salix.*
>
> *107. Cipla have neither produced an XRPD diffractogram showing that the amorphous rifaximin they allege to be present in XIFAXAN® tablets has the XRPD pattern of FIG. 1, nor have they established that the alleged amorphous rifaximin will inherently have the XRPD pattern of FIG. 1. Thus, Cipla have not proved that the amorphous rifaximin they allege to be present in XIFAXAN® tablets is the claimed amorphous rifaximin, even accepting Dr. Kaduk's evidence at face value. Since the only Valid Claims are claims [b] and [c], and both contain the FIG. 1 limitation, Cipla have not proved infringement (absent the license) of claims [b] and [c] and this is fatal to Cipla's case.*" [emphasis added]

Oral closings

60. The issue of whether it was inherent that rifaximin had the Figure 1 pattern was raised in the course of oral closings by Mr Patel for Cipla. The relevant section of the exchange was as follows:

> "*THE ARBITRATOR: … I have a product, it contains amorphous rifaximin, but the amorphous rifaximin has a different XRPD pattern from Figure 1. My question is, does that product infringe?*
>
> *MR. PATEL: If you have an amorphous rifaximin sample and the X-ray diffraction pattern of that does not reflect the amorphous rifaximin pattern of Figure 1, then it would not be covered by the claim. We do not have that. There is no factual scenario in this case, there is no factual evidence of that. I am going to point you to Salix's admission and Judge Rader's admission that when amorphous rifaximin is present, Figure 1 is an inherent property of that amorphous rifaximin.*" [emphasis added]

61. The material point in this exchange is not whether the evidence relied on by Mr Patel supported the submission (the challenge is not whether the Tribunal correctly decided the point) but the fact that Mr Patel did not say that the point had been settled by the 26 October ruling and thus was no longer a live issue.

62. More significantly the issue of the prior ruling was directly raised by Mr Saunders in his oral closings. It is important to see the exchange in full:

> "*MR SAUNDERS…I think there may have been a certain, a little bit of, there is a slight risk that when you are approaching that question of amorphous rifaximin and Figure 1, that you do so on the basis of the evidence as it was before you in the record, I think as Mr. Patel emphasised. You may recall that we had a bit of an argument, Mr. Waugh and I, before you, about whether some very late evidence could come in which suggested that there was a polymorphism so there were multiple different forms of amorphous content. You ruled that it was too late and that was to be excluded. So for present purposes, whenever you are approaching the question about amorphous content and Figure 1 and characterisation of amorphous content, then there is nothing on the record in the case that would suggest that it is anything else other than Figure 1 and that is something on which you have already ruled. I did note that in Salix's closing, at paragraph 10, there is a slight attempt to resurrect this point, but it is not open to them and there is no evidence on it. And the reason, just to recall why it was excluded, was because it was introduced so late that we did not have a proper opportunity to respond to it, so you ruled it would be put out of your mind, as it were. So I just wanted you to be ----*
>
> *THE ARBITRATOR: I understand that, but what I was wondering, and I do not know if it is the case, whether it could be argued that it was for you to show that when it comes to the claims which have a specific reference to a particular XRPD pattern, that the amorphous rifaximin in the relevant samples did have that pattern.*
>
> *MR. SAUNDERS: We do not need to do that, as this arbitration stands, because amorphous equals Figure 1 for the present purpose. So it is not as if -- that is in effect the point that you ruled against Salix on, which is that there are different forms, or the potential that there are different forms of amorphous content which might have different characterising XRPD patterns that make ----*
>
> *THE ARBITRATOR: That may depend on -- I quite accept that they cannot put in evidence that I stopped them putting evidence in on that, positive evidence in on that, but it still raises the question about whether that can be run as a "it is for you to show", rather than it is for them to show otherwise. It is for you to show that the amorphous rifaximin in these tablets had this diffraction pattern, not for them to show that there are others to show that it did not.*
>
> *MR. SAUNDERS: Yes. I think they certainly make the point that amorphous rifaximin -- that we have not shown Figure 1.*
>
> *THE ARBITRATOR: Exactly.*
>
> *MR. SAUNDERS: Yes, they say there is nothing, where do we see the Figure 1 trace in any of the evidence?*
>
> *THE ARBITRATOR: That was the point. I quite accept there is not any evidence positively to show that other amorphous -- there is more than one amorphous rifaximin XRPD pattern. But that does not quite deal with, necessarily deal with the point.*

> *MR. SAUNDERS: No. We would accept that that is a criticism that is open to them to make.*
>
> *THE ARBITRATOR: Yes.*
>
> *MR. SAUNDERS: Of course what it is not open to them to make is to say, "and the particular variety of amorphous that you have got is different to some other variety of amorphous which is not in the case". I suspect that there is actually, it is not really that much of a distinction, but it is important that we are absolutely square about the effect of the ----*
>
> *THE ARBITRATOR: If I accept that they have not -- there is no evidence to show that there is more than one form, but, anyway, we have the point.*
>
> *MR. SAUNDERS: Sir, that is the point.*" [emphasis added]

63. What is clear from this exchange is that Mr Saunders expressly and clearly advanced the proposition that the Tribunal had already ruled that "*amorphous equals Figure 1 for the present purpose*" and the Tribunal responded that, by the earlier ruling he had ruled that Salix could not put in positive evidence to show that there was more than one form of amorphous rifaximin, but that there was still a burden on Cipla to show that the amorphous rifaximin in the patent had the Fig 1 pattern.

> "*I quite accept that they cannot put in evidence that I stopped them putting evidence in on that, positive evidence in on that, but it still raises the question about whether that can be run as a "it is for you to show", rather than it is for them to show otherwise*."

64. When this point was put to Mr Saunders, he did not press the point that the issue was no longer live or that it was unfair to regard it as live in light of the way Cipla, relying on the 26 October ruling, had subsequently conducted the case. Rather he appeared to accept as a valid point both the need for evidence and the lack of evidence:

> "*THE ARBITRATOR: ...I quite accept there is not any evidence positively to show that other amorphous -- there is more than one amorphous rifaximin XRPD pattern. But that does not quite deal with, necessarily deal with the point.*
>
> *MR. SAUNDERS: No. We would accept that that is a criticism that is open to them to make.*" [Emphasis added]

65. In his oral closings Mr Waugh also addressed the issue. It is not necessary to set that out in full. However it is worth noting that in response to Mr Patel's submissions, Salix submitted that it had not admitted that the XRPD pattern in Figure 1 was an inherent property of amorphous rifaximin but that it has said that it was an inherent property of the claimed amorphous rifaximin.

66. Mr Saunders then returned to the issue in his oral Reply referring to it as the debate about "polyamorphism". The relevant sections are as follows:

> "*The way that this worked out was that Salix wanted to put in a patent late in the day that said there were multiple different polymorphs of, sorry, there are multiple different amorphous forms of rifaximin and that they had different XRPD patterns.*

We objected, you ruled on that and said it could not come in, it was too late. We also removed, in order to deal with an objection in the light of that ruling, we took out Dr. Linck's slide where she said it was an inherent property, because it just was not necessary to rely on that because we did not have to deal with this point. So there is, the evidential record in this case is there is nothing before you, sir, that says that there are different XRPD patterns for different forms, or even that there are multiple amorphous forms of rifaximin. That would have opened up a very big subsidiary issue which was raised too late for Dr. Kaduk to have dealt with…

What that pleading did not say is it did not aver that there were multiple amorphous forms with different XRPDs. It was just a general plea that you have to satisfy the burden of proof. So if he was going to raise this as the specific point, that was the time it should have been done and that was a point that is why, amongst other things, we said all this was much too late. So to suggest now that it is still okay to run the point on a sort of, "Who has the burden", "Who has not responded", "We have pulled the Linck slide", "No we have not", and so on, it does not work. And the evidence and the record before you in this arbitration is that there is, that there is one amorphous form and Figure 1 is its XRPD pattern and there is nothing more on the go.

THE ARBITRATOR: You say that is the evidence. This could be quite an important point, so let me examine that a bit. Why do you say that is the evidence? I can understand, the only evidence I have, as I see it, is that amorphous rifaximin, there is at least one type, possibly the only type of amorphous rifaximin, that has a particular XRPD pattern. Is it up to you to show that the amorphous rifaximin, if I accept Dr. Kaduk's evidence in the relevant product, is has that particular x-ray PD diffraction pattern, if it is required to have it under the terms of the patent, which again you say it is not, but let us put that to one side for the moment. Or is it for the other side to show that there are other amorphous rifaximins with different XRPD patterns? Why is the fact that they have not raised it or tried to raise it late, how does that help me to know where the onus is?

MR. SAUNDERS: Well, so the way the evidential record developed was that this was not -- so looking for different forms of amorphous rifaximin was not part of the case at all. Dr. Kaduk was tasked with looking for rifaximin, which he did by reason of the deficit.

THE ARBITRATOR: Yes.

MR. SAUNDERS: If this was a case about looking for a particular characterisation of amorphous rifaximin, then what would have been necessary was in some way to purify the rifaximin to isolate it out of the tablets and then purify it so it could be tested and then test that. That was never in issue because it was never, it was never averred against us that there were multiple forms. It was only very late in the case where there was an attempt to introduce that, because somebody had mentioned it in a patent. Nobody had thought anything about it at all until that was raised. And so at that stage, that was raised, and Dr. Linck put that point in her slide and both of them were withdrawn. So where one is left is that the experiments that had been conducted were to investigate the amorphous content. That protocol was sent to Salix a long, long time ago. If there had been a major, if there had been a problem with that, it was, we would say, rather incumbent upon them to say, "Look, you

know", they should have put in a proper pleading and said, "This is deficient because you are not looking at the right thing here at all. You should have done some chemical characterisation study, where you should have purified and done some further testing". That was never an issue at all until someone on Salix's side had a bright idea to put a last-minute patent in to suggest that there was a distinction here which had never been in the case, was not in any of their expert reports and was not dealt with by Dr. Kaduk at all. It came as a complete surprise to everybody. In those circumstances ----

THE ARBITRATOR: I think the fact they tried to put in evidence later on and did not succeed and so on, that is all irrelevant. They cannot be worse off as a result of having done that than if they had not. So the question really, what you are really saying is that if they wanted to run that argument, they should have raised it earlier?

MR. SAUNDERS: Yes, exactly that.

THE ARBITRATOR: That is why the onus, because on the face of it, I see force in the point that it is for you to show, if you are wrong on the ungranted claims and you are limited to the granted claims, and if the granted claims do require the amorphous rifaximin to be, have that particular XRPD, and if I accept Dr. Kaduk's evidence, then it can still be said that it is up to you to show that the amorphous rifaximin in question had the relevant XRPD, and you have not done that. That is Mr. Waugh's point. On the face of it, it is for you to show infringement, so that seems to me to have force. But you say, given the way the pleadings developed, and we were doing the pleadings, it was for them to plead that point rather than blindside you with it and say the onus is on you. Is that a fair summary? I do not want to ----

MR. SAUNDERS: That is a fair summary. It is a pleading point and an evidential one, in that when Dr. Kaduk did his testing, this is not something that was raised by either Dr. McClurg or Professor Myerson, so nobody was saying anything about polyamorphism or different multiple amorphous forms at any point. This is not something that was picked up in evidence.

...

MR. SAUNDERS: No, no. It is just not known. So that is where, I think, we come out on that. So we say it is not a failure to -- I mean, if you think about it, if that had been pleaded, the arbitration would have taken a very different tack evidentially, because we would have known that we would have had to have dealt with this point and we would have been having lots of arguments about whether the extent to which amorphous things tend to produce that particular XRPD or whether that was in some way a fingerprint of some particular type of amorphous thing and whether, you know, there is a more fundamental question, which is actually if something is amorphous, what does it mean to say there are different types of amorphous things? There is a sort of categorical question which, you know, amorphous means glassy and sort of devoid of structure. So having different types of amorphous things is somewhat of a surprise to the material scientist. There is quite a lot of evidential points which would need to have been dealt with and

> *none of them were picked up. That is why we say it is just too late to raise this*". [emphasis added]

Discussion

Issue no longer live?

67. In oral submissions to this Court counsel for Cipla sought to stress that the issue was polyamorphism and by the 26 October ruling the Tribunal had excluded this as an issue. It was submitted that this explained the observation by the Tribunal in the Award that Cipla's claim failed on a point on which "*relatively little time was spent in argument and even less time was spent in evidence on the point*".

68. In my view on its face the 26 October ruling was to the effect that the new evidence could not be put to Dr Kaduk.

69. The 26 October ruling contained the following passages:

> "*…In those circumstances, to raise a point which could have been raised at any time before and, if it was going to be raised, should have been raised in accordance with normal principles, and to raise it at this stage for the first time when Dr. Kaduk is about to be cross-examined, does seem to me to be unfair…*
>
> *With some regret, but bearing in mind my duty is to ensure a fair hearing, I have concluded this evidence should not be put and should not be put in and should not be put to the witness.*" [emphasis added]

70. The inference to be drawn from the face of the 26 October ruling is supported by the view expressed by the Tribunal as to the effect of the 26 October ruling at paragraph 145 of the Award:

> "*145. Salix also sought to put in late evidence, which suggested that amorphous rifaximin could produce different XRPDs, and that not all amorphous rifaximin produced a FIG 1 XRPD. I acceded to Cipla's submission that this evidence was presented too late to be admitted, and accordingly it was excluded.*"

71. This makes it clear that the 26 October ruling was a ruling that the evidence should not be admitted. Although there was reference to the issue being a new point, it was not a ruling on what issues were live.

72. Further when Mr Saunders expressly made the point in oral closing that "*there is nothing on the record in the case that would suggest that it is anything else other than Figure 1 and that is something on which you have already ruled*" this was rejected by the Tribunal as is clear from the passages reproduced above and in particular where the Tribunal noted:

> "*I quite accept that they cannot put in evidence that I stopped them putting evidence in on that, positive evidence in on that, but it still raises the question about whether that can be run as a "it is for you to show", rather than it is for them to show otherwise.*"

73. In his oral Reply Mr Saunders submitted that:

"*There is quite a lot of evidential points which would need to have been dealt with and none of them were picked up. That is why we say it is just too late to raise this*".

74. In the Award the Tribunal did address the argument that Cipla had been "*ambushed*" and rejected it as follows:

> "*148. Although the suggestion was not pressed hard, Cipla suggested that the point was something of an ambush on the part of Salix. It is fair to say that, until closing submissions, it did not appear to be a point of which a great deal was made by Salix, but, unlike many of the other points that were in contention, this is a very short point, particularly in the light of the dearth of much if any directly relevant evidence. But more importantly, the point was in fact specifically raised by Salix, as it should have been, in its Statement of Defence and Cross-Claim on 27th January 2021: in para 207, it contended that "XIFAXAN® tablets are neither 'essentially free of crystalline rifaximin' nor are they 'characterized by the XRPD pattern shown in Figure 1'", and two paragraphs later, it stated that "XIFAXAN® tablets would have to have the XRPD pattern shown in Figure 1 for Cipla to prove infringement of the 'Figure 1' limitation, and they do not".*
>
> *149. It can be said that these statements concern the XRPD pattern of XIFAXAN® tablets rather than the rifaximin therein contained, but I consider that those two paragraphs put, or should have put, Cipla on notice as to the point at issue. And, if there is still any remaining doubt, it is surely put to rest by what Salix contended in paras 136 and 139 of its Rejoinder and Defence to Counterclaim dated 6th October 2021. In para 136: "Cipla has failed to meet its burden of proving infringement of [the XRPD] claims because it does not have even a single XRPD diffractogram of XIFAXAN® tablets or its API that has the halo pattern of Figure 1" (emphasis added). And in para 139: "Cipla has not produced any XRPD of the tablets that has the pattern shown in Figure 1, and it has not proved that the amorphous rifaximin it alleges is present in the tablets has the XRPD pattern of Fig 1, rather than a different XRPD pattern" (emphasis added). It therefore appears to me that, unless it can be said to be up to Salix to show that amorphous rifaximin does not always produce a FIG 1 XRPD, or unless there is some reason for thinking that that is the case, Cipla's case that the XIFAXAN® tablets infringe the XRPD Claims must fail, because, even if those tablets contain amorphous rifaximin, Cipla has not established that any of that rifaximin has a FIG 1 XRPD. And in my view, there is no basis for saying that it is up to Salix to show that amorphous rifaximin does not always produce a FIG 1 XRPD. On a fair view of the evidence, there is no evidence to suggest even faintly that the FIG 1 XRPD is always thrown up by amorphous rifaximin. In so far as there is any evidence, it points the other way, namely in Dr Swaminathan's somewhat throw-away line in cross-examination, but in my opinion that is an insufficiently clear or tested piece of evidence on which to base any conclusion.*" [emphasis added]

Would the proceeding have been conducted differently

75. Cipla's focus before this Court was on the unfairness that in light of the ruling it conducted its case on the basis that polyamorphism was not an issue. It submitted that the lack of evidence referred to by the Tribunal in the Award resulted from the 26 October ruling and that otherwise it would have pursued the issue in cross examination.

76. However as set out above Mr Patel in his closing submissions for Cipla, rather than assert that as a result of the 26 October ruling the issue was no longer live such that Cipla did not have to deal with it, or that in the light of the ruling, Cipla had not pursued the point in evidence, Mr Patel submitted that there was evidence to establish that the Figure 1 pattern was present.

77. The Tribunal dealt with this evidence, and rejected it, in the Award:

> "*…In closing, Cipla argued that, in various passages, Salix's pleaded case and Judge Rader's declarations effectively accepted, or even contended, that amorphous rifaximin always produced an XRPD as shown in FIG 1. However, I consider that it is clear that the passages relied on were directed to the amorphous rifaximin as claimed in the relevant patents, and not to amorphous rifaximin generally…*"

78. In his submissions to this Court Mr Saunders stressed that the whole testing regime would have had to have been different had the issue been live. To the extent this submission was directed at the argument that the finding in the Award on an issue that had been held in the 26 October ruling to be no longer live was unfair and could not have been undone by raising an objection in closing submissions, this does not assist Cipla as the key point is that Cipla did not assert in closing that the issue was no longer live by reason of the 26 October ruling. As is clear from the lengthy extracts reproduced above, the closing submissions on behalf of Cipla were directed at the issue of whether it was too late for Salix to raise the issue of polyamorphism by reason of its not having raised it properly in the pleadings and the impact this had on the testing carried out by Dr Kaduk, not that the Tribunal had ruled that the issue was no longer live and this had affected the conduct of the case after the 26 October ruling.

79. To the extent that the submissions concerning the testing were directed at the submission that the ruling constrained Cipla's subsequent conduct of the case, the testing was done in advance of the merits hearing and thus did not result in any change in its approach after the 26 October ruling which could be said to amount to unfairness. This seems to me consistent with what Mr Saunders submitted before the Tribunal in his oral Reply which was directed to the testing rather than the period after the 26 October ruling:

> "*It is a pleading point and an evidential one, in that when Dr. Kaduk did his testing, this is not something that was raised by either Dr. McClurg or Professor Myerson…*"

80. It has not been suggested that in the course of his closing submissions Mr Saunders inadvertently overlooked the importance of the 26 October ruling as now advanced to this Court. In response to a question from this Court as to why he did not raise the matter at the time, Mr Saunders sought to develop an argument that it would have been impossible to reopen the evidence at that point. It seems to me however that the significance of the exchanges in oral closings is that they show that at the time Cipla did not regard the 26 October ruling as having disposed of the issue nor did it raise any objection that it had subsequently conducted its case in the light of that ruling on the basis that it no longer had to establish the presence of Fig 1 such that it would be unfair for the Tribunal to regard the point as in issue. As set out above in his oral Reply Mr Saunders said:

> "*…if that had been pleaded, the arbitration would have taken a very different tack evidentially, because we would have known that we would have had to have dealt with this point … There is quite a lot of evidential points which would need to have been dealt with and none of them were picked up. That is why we say it is just too late to raise this*" [emphasis added]

81. To the extent that in his oral Reply Mr Saunders submitted that there was any unfairness from the issue of polyamorphism being raised late, the Tribunal's response was:

> "*I think the fact they tried to put in evidence later on and did not succeed and so on, that is all irrelevant. They cannot be worse off as a result of having done that than if they had not.*"

82. In submissions to this Court Mr Saunders stressed that polyamorphism had not been advanced by Salix prior to it being raised at the merits hearing. As referred to above, this was considered by the Tribunal and fully explored in the course of oral submissions before the Tribunal. It seems to me that these are 2 sides of the coin but the distinction is important. Cipla had to prove its case that the patent was infringed. Its pleaded case was that it had the Fig 1 pattern. It could have proved that element by establishing that it is inherent that amorphous rifaximin had the XRPD pattern. The contrary is of course that if it is not the position that amorphous rifaximin necessarily has that pattern, then there must be more than one form of amorphous rifaximin. However as the Tribunal held, it was not necessary for Salix to prove polyamorphism. It was for Cipla to prove that the Figure 1 XRPD pattern was present. As the Tribunal said in the course of closing submissions to Mr Saunders (above):

> "*It is for you to show that the amorphous rifaximin in these tablets had this diffraction pattern, not for them to show that there are others to show that it did not.*"

Conclusion

83. It is important to stress that the basis for the challenge now advanced for Cipla is not that the Tribunal was wrong in its decision but that it was unfair given its earlier ruling.

84. In light of the clear exchanges in oral closings I reject the submission that by considering whether Cipla had discharged the burden of proof on this issue the Tribunal decided the arbitration on a point that was not raised as an issue or argued. The point was pleaded, Mr Patel sought to rely on evidence that the point was established and the question of what the 26 October ruling decided was canvassed in closing submissions by Mr Saunders as set out above. It is clear in my view that "*the parties have had an opportunity to address all the "essential building blocks" in the tribunal's conclusion*".

85. I find that in light of the 26 October ruling Cipla was not entitled to proceed on the assumption that the question of whether the amorphous rifaximin in the XIFAXAN® tablets produced the Figure 1 XRPD Pattern was no longer in issue but the onus was on Cipla to prove its case, not for Salix to prove polyamorphism. There was no breach by the Tribunal of its duty to act fairly and impartially and the Tribunal gave each party a reasonable opportunity of putting its case.

86. Further I find on the evidence before this Court that Cipla did not proceed on the assumption that in the light of the 26 October ruling it no longer had to establish that the amorphous rifaximin in the XIFAXAN® tablets produced the Figure 1 XRPD Pattern.

Overlooked evidence

87. In the Arbitration Claim Form the case for Cipla was advanced on the basis that the arbitrator had overlooked evidence. It was submitted in Cipla's skeleton that the Tribunal had breached section 33 in that it ignored the "common ground" reflected in the evidence of Professor Myerson and Dr McClurg and contradicted the 26 October ruling in which it excluded evidence suggesting there might be different forms of amorphous rifaximin.

88. It was submitted for Cipla to this Court that the 26 October ruling made it clear that the issue of inherency was common ground; Cipla relied on the passage in the 26 October ruling referring to the evidence of Dr Myerson:

> "*In addition, it does seem to me that passages in some of the evidence suggests that there is only one XRPD pattern for amorphous rifaximin. For instance, and perhaps most notably, Dr. Myerson says that "amorphous rifaximin is known to provide an XRPD signal. That pattern is provided in Figure 1 of Cipla's own patent". There is no suggestion there is any other pattern or signal that might be made*". [emphasis added]

89. Cipla submitted that having identified the agreed and accepted evidence to that effect in the 26 October ruling the Tribunal should not have proceeded to ignore and, indeed, contradict, that same evidence and make a contradictory finding in the Award. The corollary of this is that, if the Tribunal was going to ignore the agreed evidence, or to depart from the basis of the 26 October Ruling, it ought to have provided the parties with a full and fair opportunity of addressing it on the correctness of that approach.

90. In my view the evidence of Dr Myerson was not the subject of a binding finding on the evidence in the 26 October ruling.

91. It is not stated to be a finding on the evidence – the Tribunal merely makes reference to the evidence as part of its reasoning: the language used viz "*passages in <u>some of the evidence suggests</u>*" [emphasis added] is not a basis for concluding that the evidence was common ground or that the Tribunal was ruling on the evidence.

92. Further and arguably more significantly, this is not how Cipla regarded the ruling as is evident from its submissions by Mr Patel referred to above where Mr Patel sought to rely on the evidence of Judge Rader.

93. In my view it was not necessary for the arbitrator to make reference to this evidence in the Award: it was not relied upon in closing by Cipla, further it was not submitted for Cipla in its closing submissions that the evidence of Myerson on this point was assumed as agreed; rather different evidence was relied upon (as referred to above) and the Tribunal dealt specifically with that evidence in the Award. I note *Brockton Capital LLP v Atlantic-Pacific Capital* [2014] EWHC 1459 (Comm) at [22]:

> "*…There is also an important distinction between, on the one hand, a party having no opportunity to address a point, or his opponent's case, and, on the other hand, a party failing to recognise or take the opportunity which exists. The latter will not involve a breach of section 33 or a serious irregularity…*"

94. For these reasons I find that there is no basis to conclude a breach of section 33 in this regard.

95. Although in its oral submissions before the Court, Cipla framed its argument of "overlooked evidence" on the basis it was accepted evidence in the light of the 26 October ruling, it was also submitted for Cipla that the Tribunal had overlooked the evidence. Salix submitted that an allegation that a tribunal has ignored or failed to have regard to an aspect of the evidence in its award cannot be the proper subject of an allegation of serious irregularity under section 68: *New Age Alzarooni v Range Energy Natural Resources* [2014] EWHC 4358 per Cooke J. at [14] and *UMS Holdings v Great Station Properties* [2018] Bus LR 650. It submitted that there is no recognised exception to the general principle and Cipla had failed to identify any case in which a s68 applicant had successfully overturned an award on this basis.

96. Having reviewed the authorities Teare J in *UMS Holdings* set out his understanding of the law as follows:

> "*Having considered these authorities my understanding of the law regarding allegations that an arbitral tribunal has overlooked evidence is as follows. A contention that the tribunal has ignored or failed to have regard to evidence relied upon by one of the parties cannot be the subject matter of an allegation of a serious irregularity within section 68(2)(a) or (d), for several reasons. First, the tribunal's duty is to decide the essential issues put to it for decision and to give its reasons for doing so. It does not have to deal in its reasons with each point made by a party in relation to those essential issues or refer to all the relevant evidence. Second, the assessment and evaluation of such evidence is a matter exclusively for the tribunal. The court has no role in that regard. Third, where a tribunal in its reasons has not referred to a piece of evidence which one party says is crucial the tribunal may have (i) considered it, but regarded it as not determinative, (ii) considered it, but assessed it as coming from an unreliable source, (iii) considered it, but misunderstood it or (iv) overlooked it. There may be other possibilities. Were the court to seek to determine why the tribunal had not referred to certain evidence it would have to consider the entirety of the evidence which was before the tribunal and which was relevant to the decision under challenge. Such evidence would include not only documentary evidence but also the transcripts of factual and expert evidence. Such an inquiry (in addition to being lengthy, as it certainly would be in the present case) would be an impermissible exercise for the court to undertake because it is the tribunal, not the court, that assesses the evidence adduced by the parties. Further, for the court to decide that the tribunal had overlooked certain evidence the court would have to conclude that the only inference to be drawn from the tribunal's failure to mention such evidence was that the tribunal had overlooked it. But the tribunal may have had a different view of the importance, relevance or reliability of the evidence from that of the court and so the required inference cannot be drawn. Fourth, section 68 is concerned with due process. Section 68 is not concerned with whether the tribunal has made the "right" finding of fact, any more than it is concerned with whether the tribunal has*

> *made the "right" decision in law. The suggestion that it is a serious irregularity to fail to deal with certain evidence ignores that principle. By choosing to resolve disputes by arbitration the parties clothe the tribunal with jurisdiction to make a "wrong" finding of fact.*" [emphasis added]

97. It was submitted for Cipla that there was no absolute rule, the failure to deal with particular evidence may exceptionally be a ground for challenge under s68 and the rule does not apply where the evidence was agreed or accepted by both parties.

98. In my view even if this were to fall within any alleged exception to the general rule that the Court will not intervene, the challenge is hopeless on the facts of this case. If Cipla regarded the evidence of Professor Myerson as common ground or the 26 October ruling as determinative as to the evidence on this point, it had the opportunity to say so in closing submissions. It did not do so: it relied on different evidence as referred to above in the submissions of Mr Patel and I infer that was because it did not regard the matter as having been determined or common ground.

99. On the facts there can be no argument that the Tribunal fell into error and overlooked evidence which was common ground or determinative of an issue. The Tribunal does not have to refer to every piece of evidence and the facts of this case do not constitute any exceptional circumstances should this be sufficient as a matter of law.

Substantial injustice

100. In the light of my findings above there is no need for me to consider whether substantial injustice was caused by the alleged failings.

101. Judgment for Salix.