

Serious irregularity standard in arbitration



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In *Cipla Limited v Salix Pharmaceuticals Inc* [2023] EWHC 910, the English High Court has confirmed a high threshold exists for successful challenges to awards on the basis that the arbitral tribunal committed serious irregularity because it failed to act fairly.

Background

In a 2009 agreement (the **Agreement**) Cipla Limited (**Cipla**) licensed Salix Pharmaceuticals Inc (**Salix**) to use some of its patent claims for amorphous rifaximin in exchange for obtaining royalties on the sales. Salix sold XIFAXAN® without paying royalties to Cipla. Cipla alleged sales of XIFAXAN® breached the Agreement as the drug contained amorphous rifaximin, but Salix maintained it contained only crystalline rifaximin (and no amorphous rifaximin).

Out of five possible patents there were two valid claims to amorphous rifaximin which were granted/ issued patents and three claims

Irregularity standard in arbitration

→ In a dispute over pharmaceutical patents, the English Court of Appeal has confirmed the high standard for challenging an arbitral award based on serious irregularity.



were rejected because they had not been diligently prosecuted by Cipla. These two granted patents were the crucial focus of the argument.

The parties went to arbitration before Lord Neuberger of Abbotsbury, who produced an award dated 3 May 2022 (the **Award**). The Award found that Cipla:

1. proved the patents had amorphous rifaximin with the Figure 1 XRPD pattern, (which

means that by x-ray powder diffraction analysis a distinct halo effect was produced);

2. failed to prove that the amorphous rifaximin in XIFAXAN® produced the Figure 1 XRPD pattern; and
3. failed to prove all amorphous rifaximin showed a Figure 1 XRPD pattern.

The Award dismissed Cipla's claim for a royalty for sales of XIFAXAN® tablets under the Agreement.¹

Cipla's contentions

Cipla contended in *Cipla Limited v Salix Pharmaceuticals Inc*² that the tribunal had failed to act fairly under section 33 of the Arbitration Act 1996 (UK) (the Act) in so far as:³

- A serious irregularity emerged based on the tribunal's approach to the Figure 1 XPRD issue in a 26 October 2021 ruling (**26 October ruling**)⁴ compared to how it was

1 *Cipla Limited v Salix Pharmaceuticals Inc* [2023] EWHC 910 at [22].

2 *Cipla*, above n 1.

3 Section 33 involves a duty to act fairly, impartially and to give a party a reasonable opportunity to put their case, answer their opponent's as well as the tribunal adopting procedures suitable to the circumstances of the case.

4 Whereby late evidence of Salix's as to polymorphism (different amorphous rifaximin giving off different XRPD patterns) was excluded.

handled in its Award. Cipla alleged that in the 26 October ruling the tribunal had ruled out evidence that different types of amorphous rifaximin gave off different XRPD fingerprints. Cipla assumed it was therefore able to rely on the inherency of amorphous rifaximin to only give a Figure 1 XRPD pattern. This meant Cipla did not focus on an issue it assumed was no longer live.

- The tribunal allegedly overlooked the evidence of one of Cipla's experts.

Therefore, after the Award was issued, Cipla applied under [section 68 of the Act](#) to challenge it on the basis of serious irregularity. The relevant part of section 68 holds:

68 Challenging the award: serious irregularity.

- (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) ...

Serious irregularity standard

It is a matter of natural justice that the parties are entitled to address the *essential building blocks* of the arbitrator's Award.⁵ Nevertheless, parties face a *high hurdle*⁶ to surmount under a section 68 challenge, otherwise noted as a *high threshold*⁷ or *heavy burden*.⁸ In *Ducat* it was noted that section 68 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*.⁹

The tribunal also does not have to refer to every piece of evidence:¹⁰

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.

High Court decision

The High Court found for Salix in that the Award was not based on evidence or an issue which was not raised or argued. The Judge, Dame Moulder DBE, found that the 26 October ruling did not decide what issues were live in the arbitration. Cipla was still charged with proving to the civil standard that rifaximin in XIFAXAN® gave off Figure 1 XRPD patterns. Cipla failed to do this, hence the Award.

A secondary argument Cipla raised was that the tribunal had accepted its evidence in the 26 October ruling then overlooked or contradicted it in the Award. The Judge found that the tribunal had set out the *essential building blocks* for its decision and could not be faulted even if it did not refer to every piece of evidence.¹¹

Conclusion

The English Courts will rarely intervene when a section 68 application arises. Something where the tribunal has *gone so wrong* as to require judicial correction is required. This case did not reach that standard by any measure. This case emphasises that England and Wales is an arbitration-friendly jurisdiction and that counsel should be clear in argument to clarify what issues need addressing, then address them.

5 *QAO Northern Shipping Co v Remolcadores De Marin SL* [2007] EWHC 1821 at [23].

6 *Ducat Maritime Ltd v Lavender Shipmanagement* [2022] EWHC 766 at [23] [**Ducat**].

7 *Lesotho Highlands Development Authority v Impregilo SpA and Others* [2006] AC 221 at [28].

8 *New Age Alzarooni 2 Ltd and Another v Range Energy Natural Resources Inc* [2014] EWHC 4358 at [12].

9 *Ducat*, above n 6, at [23].

10 *Cipla*, above n 1, at [99].

11 *Cipla*, above n 1, at [96].