

EIP

Astellas' Validity Success Not Enough to Catch Competitors' Products on Overactive Bladder Treatment

The High Court has handed down its judgment in *Astellas v Teva and Sandoz* regarding Astellas' patent covering treatment for overactive bladder. The High Court found Astellas' patent valid but not infringed by Sandoz's generic product. Teva admitted that their original generic product infringed, but that their revised product did not. The Court ran out of time before it could determine infringement of Teva's revised product.

Background and Issues

This litigation is part of a series involving the active ingredient mirabegron, for the treatment of overactive bladder syndrome. Astellas alleged that generic mirabegron tablets proposed to be launched by Teva and Sandoz would infringe EP(UK) 2,345,410 (the "Patent"). Teva and Sandoz (the "Defendants") each counterclaimed for revocation of the Patent on the grounds of obviousness, insufficiency and added matter.

The Patent

The Patent relates to a pharmaceutical composition which has the ability to reduce food effects by combining an active ingredient with specific ingredients to control a releasing rate of the active ingredient. Claim 1 was the claim in issue.

Validity

The validity issues took up a large amount of trial time as noted by the Judge. On

insufficiency, the Defendants alleged that there was excessive claim breadth and there was ambiguity or uncertainty. The Judge set out the jurisprudence on plausibility and provided a lengthy discussion on the arguments set out by each of the parties. As a result of the in-depth analysis and the Judge's view on construction, the Judge concluded that the Defendants' insufficiency attack failed.

On obviousness, the Defendants put forward three pieces of prior art. Again, the Judge undertook a deep analysis and found that on his construction the Patent was not obvious over any of the pieces of the prior art.

On added matter, the issue had been put to one side by the time of written closings. The Defendants submitted that the added matter attacks had served their purpose in limiting the ways in which Astellas was able to pursue its case and so they no longer needed to be pursued. However, the Defendants explicitly reserved their position on added matter in the pending opposition proceedings and in proceedings in other jurisdictions.

Infringement

Teva did not contest infringement by its original product, but it brought a claim for a declaration of non-infringement in respect of a new product. However, there was insufficient time to determine this issue at trial and the parties agreed it was an issue to be determined later, if necessary.

Sandoz did not admit infringement and the Judge found there was not infringement on the deemed construction of claim 1. As a closing remark, the Judge stated that Astellas did not attempt to establish infringement, either directly or by inference via expert evidence. This remark may provide an insight into the evidence before the Judge and could explain why Astellas made a specific disclosure application against Sandoz at the end of trial.

In what was an unusual turn of events, and described as further excitement by the Judge, following oral closing from Astellas' lead counsel on the last day of the summer term at the end of a full day, the lead counsel informed the Court that his junior would be addressing "a couple of infringement issues". The junior counsel proceeded to make an oral application for specific disclosure against Sandoz without any application notice or evidence or any notice in general. The Judge directed that a formal application be made. Following to-ing and fro-ing between the parties after the trial with replies and listing the application for late February 2023, Astellas then withdrew their application in early February. Sandoz contend that the application was an abuse of process. We may see this aired at the form of order hearing with Astellas at risk of some cost consequences.

The Judge made it clear in his concluding remarks that although he had rejected the Defendants' insufficiency arguments on the basis that the Patent makes it plausible that a reduction in food effect is achieved across the breadth of claim 1 i.e. there was a reasonable prediction that the invention would work. The threshold for proving infringement is higher, and that here, at least some reduction in food effect should have been demonstrated, which Astellas failed to do.

The Judge added an apology at the end of his judgment for the length of time it had taken to produce the judgment (some 14 months after the trial took place in the summer of 2022), which fell well short of what parties are entitled to expect from the UK Patents Court. The root cause being the time taken to produce the FRAND judgment in *Interdigital v Lenovo*.

Take Away Points

The Judge provides a useful summary of the law on plausibility and its relevance to claim breadth. This case is a reminder that the thresholds for establishing plausibility and infringement are different. The patentee may have enough information in the patent to pass the threshold of plausibility across the breadth of the claim by being able to exhibit that there is a reasonable prediction that the invention will work. But that does not mean a similar indication in the alleged infringing product is sufficient to establish infringement. The threshold to prove infringement is higher, and a patentee must provide real life examples of infringement before it can stand a chance of being successful in a finding of infringement.

The judgment is available here at [Astellas Pharma Industries Ltd v Teva Pharmaceutical Industries Ltd & Ors \[2023\] EWHC 2571 \(Pat\)](#)