

EIP

Court of Appeal affirms death of Bayer's blood clotting patent in expedited hearing

The Court of Appeal announced at the conclusion of the hearing, on 16 May 2024, that Bayer's appeal in the rivaroxaban litigation against a finding of invalidity following challenges by a number of generic pharmaceutical companies, which we have previously reported on ([link](#)), would be dismissed with reasons to follow. Lord Justice Arnold taking the lead in this judgment has now provided the Court of Appeal's reasoning.

Background

The High Court found Bayer's patent, which claims the use of rivaroxaban for the treatment of thromboembolic disorders for once-daily oral administration to a human patient, invalid for lack of inventive step over two pieces of prior art which were cited as "Harder" and the "Kubitza posters". Bayer had already obtained a preliminary injunction from the High Court ahead of expiry of its compound patent on 1 April 2024, which we have previously reported on ([link](#)). The interim injunction was due to last until the hand down of the High Court judgment (12 April 2024) but the judge then extended it until 29 April 2024 in the form of order hearing heard of the same day. 29 April being the deadline for the Court of Appeal to make its decision on whether to grant Bayer permission to appeal the High Court's decision.

The Court of Appeal gave permission to appeal and extended the preliminary injunction until that hearing. Given the number of generic pharmaceutical companies interested in entering the rivaroxaban market and it being Bayer's largest-selling drug, the Court of Appeal expedited the appeal and it was heard on 16 May 2024.

Issues

Bayer, as the appellants, were only given permission to appeal on two grounds, grounds 1, broken into three sub-grounds, and 5. As a result of having grounds 2, 3 and 4 refused, Bayer applied for permission to amend their grounds of appeal to raise a new ground (the “**Application to Amend**”). During the appeal hearing, Bayer’s counsel also advanced a further ground in oral argument without applying to amend Bayer’s grounds of appeal (the “**Unpleaded Ground**”). The Court of Appeal heard full argument on this despite the absence of any amendment application.

The Application to Amend

Bayer’s submissions revolved around the judge’s misunderstanding, misinterpretation and inconsistent approach of the evidence before him, which allegedly meant his assessment of obviousness was incorrect. In Bayer’s Application to Amend, the emphasis was that the judge had inferred too much into the status in the field of three of the authors of the Harder prior art (Dr Harder, Dr Misselwitz and Professor Breddin), leading to the skilled team simply taking the authors’ statements at face value. Lord Justice Arnold did not accept this submission, and instead found that the first instance judge’s findings were correct and rationally supported by the evidence before him.

Grounds 1(1) and 5

In assessing the likelihood of success, Bayer claimed that the judge erred in law and principle by failing to apply the correct standard when considering the cited prior art together with the common general knowledge at the priority date (ground 1(1)) and that he failed to grapple with the key question of whether the skilled team would have a reasonable expectation of success based on the prior art (ground 5). Lord Justice Arnold did not accept these submissions on the premise that Bayer were misreading what the first instance judge was saying and not following his reasoning, nor had any error of principle been identified for ground 5.

The Unpleaded Ground

Bayer also claimed that the first instance judge’s acceptance of the respondents’ evidence was inconsistent as he seemed to have accepted the respondents’ experts’ evidence (one being an expert clinician and the other an expert pharmacologist) but went on to reject part of the respondents’ expert clinician’s evidence later in the judgment. Lord Justice Arnold did not accept this argument and reminded everyone that it is commonplace in patent cases for judges to accept the main thrust of expert witnesses’ evidence without accepting their evidence on every point. Additionally, the rejected part of

evidence did not impact the pharmacologist's evidence.

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Grounds 1(2) and (3)

Bayer submitted that the first instance judge erred in placing weight on Bayer's decision not to adduce "invention story" evidence in this jurisdiction, having done so in other jurisdictions. Lord Justice Arnold did not believe this to be correct and that the judgment made clear that the first instance judge did not place any weight on the absence of "invention story" evidence in reaching his conclusion as to obviousness. In fact, obviousness is to be objectively assessed from the perspective of the skilled person or team and the manner in which the inventor(s) actually gets to the invention is legally irrelevant.

Conclusion

The Court of Appeal concluded that the first instance judge made no error of principle in his assessment of obviousness. His conclusions were rationally supported by the expert evidence before him.

The judgment is available [here](#).