EIP

Blood drains from Bayer patent as it is found to be non-inventive

We previously reported on Bayer's application seeking an interim injunction against a number of generics companies to protect its rivaroxaban product (link) ahead of the imminent judgment on validity of the patent EP (UK) 1 845 961 (the "**EP 961**"). That judgment has now been handed down, with the Judge finding the EP 961 invalid for lack of inventive step.

Background

By way of recap, the case revolves around rivaroxaban. It is used for the prevention or treatment of thromboembolic disorders. Bayer own two patents that cover rivaroxaban and so have had the rivaroxaban market to itself, selling the product under its brand name Xarelto. The compound patent expired on 1 April 2024. The EP 961, which in broad terms, covers the use of rivaroxaban for the manufacture of tablets for once-daily oral administration to a human patient, was due to expire in January 2026.

Six separate invalidity actions were brought against Bayer by a number of generics for the EP 961. These were joined for trial where the Court assessed the validity of the EP 961.

Issues

The generics alleged that the EP 961 lacked inventive step over the cited prior art and that its specification was insufficient. The allegations of insufficiency were based on issues of plausibility.

Inventive Step

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It was agreed that the Pozzoli test was the correct approach in assessing inventive step and that, on the present facts, the relevant criterion for obviousness was whether it was " obvious to try with a reasonable expectation of success." Here, in particular, whether it was obvious to the skilled person to carry out phase II trials, which included once daily dosing based on the data from the phase I trials presented in the cited prior art.

The court grappled with the public interest in producing new drugs that have been through the appropriate clinical testing against the ethical barrier and particularly risks to individuals involved in the clinical trials, including phase II trials. However, given that in the real world, the ethical question would be resolved by an ethics committee rather than the skilled team, the Court considered, for the present case, whether the skilled team would have thought that it was worth applying to the committee for permission to conduct a phase II trial which included a once-daily regimen with a reasonable expectation that the committee would give permission, and whether it was likely that permission would be given.

On the evidence put before it, the Court found that the EP 961 lacked inventive step over the cited art: Harder (a research poster) and the Kubitza posters. All were materials created and published by researchers working with or for Bayer on the early stages of Bayer's rivaroxaban project and cited data from phase I studies. In light of the data in Harder and the Kubitza posters, the skilled team would have hypothesised that the relevant molecule was suitable to be orally administered once daily. Additionally, the skilled team would have believed that conducting a phase II trial would not have caused an unacceptable level of risk. And thus, the skilled team would have found it obvious to conduct a phase II trial which included a once daily administration regimen. This was sufficient for the Court to reach a conclusion that the EP 961 lacked inventive step over Harder and the Kubitza posters.

Insufficiency

The generics were unsuccessful with their allegations of insufficiency. They had pleaded that the claims contained no limitation as to: 1) dose or 2) types of thromboembolic disorders.

On dose, the Court found that the skilled team would have been able to carry out the claimed invention across the scope of the claims with the existing specification and the CGK.

On the types of thromboembolic disorders, the EP 961 specification lists a long list of

disorders. The majority of which were thromboembolic disorders with additional disorders being inflammatory diseases, microvascular diseases and Alzheimer's disease.

The Judge believed that the presence of the additional disorders would have been recognised as an obvious mistake by the skilled team. And as such, the skilled team would have ignored the mistake which would still allow them to construe the claims sufficiently.

Judge's Comments on the Experts

The Judge made two comments on practice points in relation to the experts in this case. The first was that when an expert is too qualified relative to their corresponding person skilled in the art, as in this case, it is important that the expert identifies their own prior knowledge.

The second was a reminder that when you have more than one expert providing evidence that interrelates, it is important that the experts consult each other's respective evidence so that they may have a full appreciation of points being made and how this may impact their own evidence. The Judge likened this to how real-life experts would collaborate in pursuit of a project.

The judgment is available here.