

# Court of Appeal refuses to impose a special test for obviousness for therapeutic use patent cases

---

- Court of Appeal upholds decision of High Court that patent owned by Genentech is invalid for obviousness
- Court rejects argument that where a claim relates to a drug combination to achieve a claimed clinical effect, there must be a very high expectation of success in order for the invention to be "obvious to try"
- The test for obviousness remains flexible, multifactorial and case-specific

## What's it about?

The appellant Genentech owned a patent relating to the use of the antibody trastuzumab (better known by its trade name Herceptin) in combination with a taxane (a chemotherapeutic agent) for the treatment of breast cancer. The respondent, Hospira, sought revocation of the patent on the grounds that the claim lacked an "inventive step" in the light of one item of prior art. The prior art was a review article describing a Phase III clinical trial of trastuzumab in combination with chemotherapeutic agents.

An invention may lack an inventive step if it would be obvious to the skilled person to try the invention. However, this only applies where there is a fair expectation that such a trial will be successful. The Court of Appeal held that the trial judge had been correct in his assessment that the trial of both treatments in combination was "obvious to try" because there was a "fair expectation of success" based on the prior art publication.

## Why does it matter?

Genentech tried to establish that where a claim relates to the use of a drug or drug combination to achieve a claimed clinical effect, in order for it to be deemed "obvious to try" it was necessary for there to be a "very high expectation of success" – it ought to be "more or less self-evident that it would work". Floyd LJ rejected this submission: there was no need to impose a special rule for claims which include as part of their technical subject matter a therapeutic effect or benefit. The correct test is a flexible one based on asking whether there is in all the relevant circumstances a fair expectation of success.

## Now what?

The judgment contains a useful summary of the authorities in relation to the complicated question of "obviousness", which has not frequently been considered by the Court of Appeal. With this judgment, the Court has reemphasised that the assessment for obviousness is a flexible one which must take into account a number of factors, and the specific facts of each case. The Court was unwilling to formulate a test for obviousness which would make a special case of therapeutic use claims.

[\*Hospira UK Ltd v Genentech, Inc. \[2016\] EWCA Civ 118\*](#)

For further information on this or any other IP related matter please contact [Emma Armitage](#) on 0207 788 5007