

The UK decides on Obviousness for combination Pharmaceuticals

Teva v. Leo, a recent case before the UK patents court, sheds some new light on the UK approach to the inventiveness of combination pharmaceutical products.

The case related to a topical formulation for treating psoriasis, containing two products that were previously only known as part of separate formulations for this purpose: betamethasone and calcipotriol.

The arguments

According to the patent owner, Leo, before the filing date of the patent there was a belief amongst dermatologists and formulators that these two products could not be combined in the same formulation as they have different pH requirements. The solution set out in the patent was to combine them in an ointment (which is non-aqueous so the effect of pH is minimised), and to use a particular solvent: poloxypropylene-15-stearyl ether, to stabilise the formulation. Leo provided extensive evidence to show that the combination formulation was more effective than either monotherapy.

The claimant, Teva, argued that the patent was obvious because the skilled person would have been motivated to combine the two products in a single formulation to hopefully increase patient compliance with treatment regimens. They also said it would have been obvious that the combination formulation would be more effective since betamethasone and calcipotriol were often co-prescribed more effective therapy was achieved by using both.

With respect to the solvent, Teva provided a document published around 20 years before the patent filing date, which disclosed that poloxypropylene-15-stearyl ether could be used as a solvent in a non-aqueous formulation comprising a corticosteroid, such as betamethasone. They argued that this would motivate the skilled person to use this solvent.

The decision

The judge decided that all of the patent claims were obvious.

He agreed with the claimant that the combination of betamethasone and calcipotriol in a single formulation was obvious and that the synergistic effect would have been expected.

The debate therefore centred around whether or not the skilled person would use poloxypropylene-15-stearyl ether as the solvent. Evidence from expert witnesses showed that this solvent was relatively unknown at the filing date. The judge reasoned that a formulator aiming to make a new formulation would test a number of different solvents too see which works best and that there was no reason why poloxypropylene-15-stearyl ether should not be included in this list of tested solvents in view of the cited evidence. He therefore found the claims to be obvious, essentially because it would have been obvious to try the claimed formulation.

The lessons

This decision is interesting because it supports an "obvious to try" approach that has been rejected in other UK pharmaceutical decisions, most notably *Conor vs Angiotech* (in which Forresters acted for Angiotech). In that decision, the judge found Angiotech's patent to be inventive because although the claimed taxol/polymer combination may have been an obvious combination for the skilled person to test, they would have had no reasonable expectation of success. In *Teva vs. Leo*, the judge does not appear to have considered whether the skilled person would have a reasonable expectation that poloxypropylene-15-stearyl ether would be a successful solvent in the relevant formulation.

This decision suggests that the UK courts may be reverting to the "obvious to try" approach to inventive step. This approach can often be unfair to pharmaceutical products which are either combinations of known products, or based on incremental development steps that involve testing multiple combinations.

On the other hand, this decision shows that the UK court could be becoming more open to "unusual" obviousness attacks. In this case, an obviousness attack based primarily on common general knowledge and subsequently drawing evidence from a prior art document, rather than the other way around, was successful.