

Is it obvious to try? Only if you can expect success

With advances in laboratory mechanisation and automation, it has become more straightforward to screen large numbers of substances for a desired activity or property. This trend has not gone unnoticed in the courts, and in some areas it has become more difficult for patentees to convincingly argue that their selection of a known compound for a particular use is inventive.



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In a recent case before the Court of Appeal of England and Wales, LEO Pharma appealed against the revocation of its two European (UK) patents directed to a new ointment for treatment of psoriasis.¹ The ointment combined two, previously known, active ingredients together with a commercially available solvent. The two active ingredients were both already used individually for the treatment of psoriasis, but had to be used separately because of stability problems. In short, the two active ingredients were only stable in aqueous environments in narrow, non-overlapping pH ranges. The two active ingredients have different beneficial effects, and so for some patients, psoriasis was treated by alternately administering the active ingredients in separate ointments.

LEO Pharma recognised that it would be useful to provide both active ingredients in a single ointment, and overcame the stability problem by using a particular non-aqueous solvent as a carrier instead of using an aqueous composition.

In an earlier hearing of the case before the High Court, it was held that it was common general knowledge that it would be desirable to combine the two active ingredients in a single ointment, and that the use of the non-aqueous, non-toxic solvent required by the claims was obvious to try. The successful

revocation argument was partly based on the disclosure in a prior art document that the claimed solvent could be used with one of the active ingredients.

However, the Court of Appeal reminded the parties that the question is not merely 'would it be obvious to try' the solvent, but instead 'would it be obvious to try it and would the skilled person have a reasonable expectation of success.' LEO convincingly showed that there was no such expectation of success in this case, arguing amongst other points that the claimed solvent was not commonly used for topical pharmaceuticals, and that not all non-aqueous solvents actually worked. In particular, propylene glycol, which on the face of it appeared to be a promising candidate as a solvent for the composition, was not suitable. In its decision, the Court of Appeal concluded that LEO Pharma's claimed ointment was inventive and overturned the High Court's decision on revocation.

In this case, the Court of Appeal followed the UK 'Pozzoli'² approach to obviousness. However, it was also noted that following the Problem and Solution approach led to the same result. In particular, it was found that the prior art document disclosing the use of the claimed solvent with one of the active ingredients would not be considered to be the closest prior art on

the basis that it is not concerned with the purpose of the invention.

The outcome of this case will no doubt be heartening to patentees, and will serve as a useful clarification for third parties (who may be considering their freedom to operate) that, to be successful, an inventive step attack will require more than simply finding a combination of common general knowledge and one or more prior art documents that taken together make the subject matter of the claim a theoretical possibility. Instead, the skilled person needs to have a reasonable expectation of success with the combination.

¹ *Teva v LEO Pharma* [2015] EWCA Civ 779

² *Pozzoli v BDMO* [2007] EWCA Civ 588, [2007] FSR 37

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