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Obvious to try attacks remain topical even if they take a different path

Brian Cordery, Gregory Bacon (Bristows) · Wednesday, October 15th, 2014

The English Patents Court (Birss J) recently demonstrated a somewhat unconventional approach to answering the statutory question of obviousness when assessing inventive step*. The judgment also provides some guidance on the role of commercial as opposed to technical considerations, in particular regulatory concerns, when assessing obviousness. Leo Pharma, the defendant in these proceedings, market a successful product in the UK under the brand Dovobet Ointment. Teva sought to revoke two patents in Leo Pharma's name which protect the Dovobet Ointment product. Leo Pharma in turn claimed infringement of the two patents by Teva's proposed generic version of the ointment, which was not contested by Teva.

The patents (EP (UK) 1 178 808 and EP (UK) 2 455 083) claimed a combination pharmaceutical composition comprising at least one vitamin D analogue (such as calcipotriol) and one corticosteroid (such as betamethasone) alongside a specified solvent. Although insufficiency and added matter were pleaded, the case turned on Teva's allegation that the patents lacked inventive step. Readers will be familiar with the English Courts' structured approach to assessing obviousness, which is not entirely aligned with the problem-solution approach adopted at the EPO**, not least because the English system does not require the identification of a closest piece of prior art.

At the heart of the case was Teva's allegation that it was obvious to use a particular compound (Arlamol E) as a solvent for a non-aqueous calcipotriol/betamethasone fixed combination ointment formulation for dermal use to treat psoriasis. The case was unusual as Teva's starting point was the common general knowledge of the person skilled in the art, from which could be derived an obvious desire to develop a fixed combination of calcipotriol and betamethasone. The use of Arlamol E in the claimed combination was then alleged to be obvious as that solvent, although not part of the common general knowledge as such, was described in the cited prior art in relation to steroids. This is the reverse of the usual position in English patent cases, where the obviousness attack starts from the cited prior art document, supplemented by the common general knowledge where appropriate. The judge held that this unusual approach was legitimate in the present case, although might not be in all cases.

Birss J found that the advantages of a fixed dose combination, and thus the idea of such a combination, were entirely obvious. The skilled clinician would expect it to improve patient compliance and that it would be an effective treatment, assuming that a stable formulation could be produced. As to formulation, the question of obviousness turned on the choice of solvent. On the

evidence, the Court decided that the skilled formulator would carry out routine compatibility tests on a number of solvents. Arlamol E was not a compound that the skilled formulator would be aware of as part of their common general knowledge. The patentee argued that the solvent had not been used widely in pharmaceutical formulations before and thus that the skilled formulator would be discouraged from including it in the routine testing as that would add potential cost, time and uncertainty to the subsequent regulatory process.

There is some support in the jurisprudence for the proposition that commercial considerations are factors that may play a role in the thinking of the person skilled in the art. The judge in the present case held that uncertainties surrounding the regulatory process in the pharmaceutical field were capable of playing a role in the person skilled in the art's thinking as a matter of principle, but that their significance would vary from case to case. Moreover, as they were commercial considerations rather than directly technical, they were unlikely to outweigh technical considerations in any but the strongest cases.

The Court held that the information in the cited prior art on Arlamol E would be encouraging and there was no ostensible reason why a product containing the solvent might fail to obtain regulatory approval. Furthermore, although not widely used in the pharmaceutical sector the compound was listed in the FDA's Inactive Ingredient Guide, which meant that the compound had been approved for use by the FDA. The Court decided that a skilled formulator considering the compound would find this reference and would thus take comfort from it.

In summary, the judge held that in "*In any real project regulatory considerations will always play a part but in my judgment in this case the regulatory factors are not sufficiently strong to have any material bearing on the decisions made by the skilled formulator*." Having failed to identify any significant regulatory prejudice against testing the solvent, Birss J also held that there were no technical reasons to doubt that it would work in the way taught in the prior art and thus there were sufficient grounds to include it in pre-formulation tests. There was also sufficient prospect of a positive result in the tests to make it worth testing. The use of Arlamol E was therefore 'obvious to try' with a sufficient expectation of success and the patents were held to lack inventive step.

There is an interesting passage at the end of the decision in which Birss J records that he has reflected on whether the conclusion he has reached falls foul of the so-called **Technograph** principles – referring to a House of Lords decision from 1972, in which it was emphasised that hindsight must be avoided in assessing the issue of inventive step. Although not openly referring to the decision, Birss J. may have had in mind the guidance from Floyd J in **Gedeon Richter v Bayer (2011)** in which the latter held: "*I think that the guiding principle must be that one has to look at each putative step which the skilled person is required to take and decide whether it was obvious. Even then, one has to step back and ask an overall question as to whether the step by step analysis, performed after the event, may not in fact prove to be unrealistic or driven by hindsight*". It is not yet known if Leo Pharma will appeal.

*Teva UK Ltd & anor v Leo Pharma A/S & anor [2014] EWHC 3096 (Pat)
**The well known Windsurfing/Pozzoli four-stage approach

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