

# Kluwer Patent Blog

## Shedding Further Light on Obviousness – the Schering/Richter case

Brian Cordery (Bristows) · Tuesday, April 19th, 2011

In a judgment dated 17 March 2011 reported at [2011] EWHC 583 (Pat), the English High Court has upheld certain claims of two patents (deriving from the same ultimate parent application) for the formulation of Ethinylestradiol (“EE”) and Drospirenone (“DSP”) used in contraception. The patents in issue belonged to Bayer Schering Pharma AG. The Hungarian company Gedeon Richter plc sought to revoke these patents on the grounds that the patents were invalid for added matter and/or obviousness. After hearing a trial which was argued over six days, Floyd J. held that several of the key claims of Schering’s patents were valid.

The judgment is interesting for at least three reasons:

First, it is a further instance of pharmaceutical formulation patents being upheld by the English Court. Until the middle of the last decade, the English Patents Court had a reputation for invalidating patents in the pharmaceutical field other than patents for new chemical entities. This is plainly no longer the case. Now it is clear that the Judges will approach all issues in a patent trial with an open mind which results in litigants leaving the Court with the sense that the issues have been properly considered regardless of the eventual outcome.

Secondly, the judgment makes clear the distinction between common general knowledge on the one hand, and information which, although not part of the common general knowledge, would be information that the skilled person faced with the problem to which the patent is addressed would acquire as a matter of routine on the other. Thus, if the invention relates to a formulation of a compound, X, then if it can be shown that a formulator would, as a matter of routine, find out certain information about X, such as its solubility in water at various temperatures and at various pHs, then it is legitimate to take that information into account when assessing the obviousness of a particular formulation regardless of the fact that it is not “common general knowledge” in the strict sense or information contained in a specific prior art citation. Thus, in a simple scenario where a challenger contends that a formulation patent for X is obvious over prior art citation P, the Court when assessing obviousness will be able to take into account the common general knowledge (as strictly defined in e.g. *Beloit v Valmet* [1997]) plus any information which it can be proved that a formulator would as a matter of routine find out about X plus information disclosed in P. Presumably, the category of information gathered as a matter of routine includes all information and not just that which would encourage the skilled person to take the steps leading to the invention in the patent. Thus, if a formulator would find out as a matter of routine that X was highly insoluble in water at high pH, this might deter him/her from proceeding down several lines

of research.

Finally, the decision includes some useful observations on the issues of both added matter and inventive step. In relation to added matter, Floyd J. relied on Arnold J.'s decision in Abbott v Medinol [2010] EWHC 2865 in which the latter was held to have “compendiously summarised” the law. In Schering, Floyd J. boiled down the passages in Abbott to four short statements which may well be seized upon by text-book authors looking for a concise yet informative summary of this difficult area of the law. In relation to inventive step, Floyd J. considered most of the recent authorities including Pozzoli v BDMO [2007], Conor v Angiotech [2007] and Generics v Lundbeck [2007] before concluding: “*where, therefore, the evidence reveals that to arrive at the invention, the skilled person has to embark on an experiment or series of experiments where there was no expectation of success, the conclusion will generally be that the invention was not obvious.*” The Judge also 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.*”

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