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Gedeon Richter plc v Bayer Schering Pharma AG [2012] EWCA Civ 235

Brian Cordery (Bristows) · Monday, April 2nd, 2012

Last April we reported the case of [Gedeon Richter plc v Bayer Schering Pharma AG \[2011\] EWHC 583 \(Pat\)](#), concerning immediate release formulations of a combination contraceptive product containing the steroidal hormones drospirenone and ethinylestradiol. We can now report the decision of the Court of Appeal in this case (handed down on 7 March 2012) where the court has clarified the test to be applied when evaluating patent amendment on the grounds of added subject matter. The court has also given guidance on the test for obviousness in circumstances where it is argued that the invention covered by the patent would have been “obvious to try”.

But first, a quick recap of the facts of the case:

Richter (a Hungarian company) applied to have two Bayer patents (EP (UK) 1 380 301 and EP (UK) 1 598 069) revoked for invalidity. One of the grounds of invalidity was that the patents were obvious in respect of various items of prior art. At trial, the court held some of Bayer’s claims were invalid for obviousness but not for added subject matter. In particular, Floyd J held:

- (i) Claims 1 and 19 of the 069 patent were invalid for obviousness but he permitted amendment to remove claims 1 to 5 and make claim 19 dependent of claim 6;
- (ii) Claim 6 of the 069 patent was not invalid for obviousness;
- (iii) Claim 1 of the 301 patent was not invalid for obviousness; and
- (iv) The 301 and 069 patents were not invalid for added matter.

Richter appealed the judge’s findings on points (ii), (iii) and (iv). Unfortunately both the added matter and obviousness arguments were rejected by the Court of Appeal and so the trial judge’s decision was held to be correct in every material aspect.

The appeal was heard by a panel of three judges including the recently promoted Kitchin LJ and Sir Robin Jacob (who retired in 2011 but who remains very active in the field and who came back to form part of the panel for this appeal). The judgment was a joint piece of work.

Added matter

With regard to the added matter challenge, the Court of Appeal held that Floyd J had correctly followed the test laid out in *Bonzel v Intervention Ltd* (No.3) [1991] R.P.C. 553 whereby the court must: 1) ascertain through the eyes of the skilled addressee what was disclosed, both explicitly and implicitly in a patent application, 2) do the same for the patent as granted, and 3) then compare the

two disclosures and decide on whether any subject matter relevant to the invention has been added or deleted.

The parent patent included the following wording in relation to a composition in a particular dosage range: “*The composition of the invention may be formulated in any manner known in the pharmaceutical art.*” In a divisional patent the claim had been amended to specify a particular dissolution rate. Whilst the meaning of the sentence certainly changed, it did not constitute added matter; the particular methods described in the disclosure were provided in the examples and the parent application also taught that rapid dissolution could be achieved by any method known in the art.

The Court held that Floyd J plainly had in mind that subject matter would be added unless it was clearly and unambiguously disclosed in the application either explicitly or implicitly. He had also correctly distinguished between what was disclosed and what was obvious (which could not be). In the circumstances, the judge’s findings were on the mark.

Regarding obviousness

The Court relied on the test set out by Lord Hoffmann in *Conor v Angiotech* [2008] UKHL 49, whereby in order for an invention to be invalid on the grounds that it would have been “obvious to try”, there must be a fair expectation of success. What constitutes a fair expectation depends upon the particular facts of the case. On the facts of this case, the Court of Appeal found that there was no (or only the slightest) expectation of success. Both parties agreed that, whilst it would have been obvious to carry out in vitro pre-formulation testing, such tests would have been performed in ignorance of the outcome and whether any specific formulation approach would have a fair expectation of success. Thus it was held that: ‘The step from Krause [the key piece of prior art] to the invention would have been more of a speculative jump in the dark than anything else.’ The patent was found to be inventive over the prior art.

Crucially, the Court also relied upon the absence of a clear explanation as to how the claimed formulation worked, even long after the patent was filed. Kitchin LJ and Sir Robin Jacob commented, “if something is inexplicable even after it is known, it is all the more unlikely to have been predictable (and thus obvious) before.” Thus, it is a strong argument in support of inventive step if the skilled addressee cannot explain why the invention works at the priority date and even more so, if it remains shrouded in mystery long after the patent is filed.

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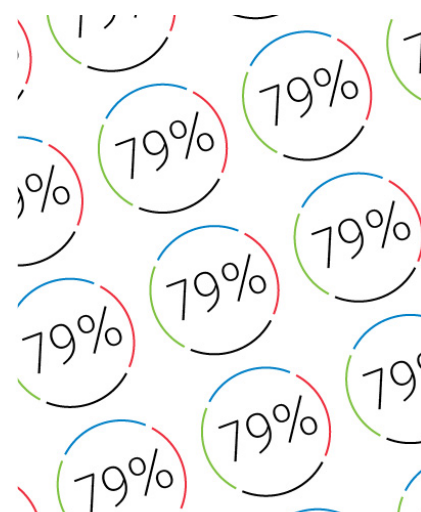
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