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Inventive activity: Motivation, the key question

Miquel Montaña (Clifford Chance) · Monday, July 30th, 2012

On 9 July 2012, Commercial Court number 2 of Barcelona dismissed a revocation action filed by two Spanish companies against patent EP 907,364, which protects a sustained-release formulation of quetiapine. To sum-up, this formulation comprises a gelling agent such as HPMC and quetiapine or a pharmaceutically acceptable salt thereof, together with one or more pharmaceutically acceptable excipients. This medicinal product is used to treat schizophrenia and bipolar disorders. The plaintiffs questioned the inventive activity of the patent using a two-tier line of argument. First, the person skilled in the art would have been motivated to develop a sustained-release formulation of quetiapine. According to them, at the priority date sustained-release formulations were particularly desirable for treating psychiatric diseases due to the compliance difficulties with this type of patient. They added that a sustained-release formulation would allow patients to take one tablet a day only, which would improve compliance. Second, using a gelling agent such as HPMC for the purpose of preparing a sustained-release formulation would have formed part of the expert's common general knowledge. These two premises, taken together, would have made the invention obvious to the person skilled in the art.

The patentee contended that at the priority date quetiapine had not even been authorized as a medicinal product. So the skilled person would not have been motivated to develop a sustained-release formulation, which is normally more costly and cumbersome, when there was no clinical experience with the immediate-release formulation in the first place. As to the technological angle of the case, the plaintiff alleged that the use of a gelling agent for the purpose of preparing a sustained-release formulation of an active principle such as quetiapine would have been just one of a wide array of technological options that the skilled person could have used.

In its judgment of 9 July 2012, which is not final, Commercial Court number 2 of Barcelona came to the conclusion that the crux of the matter was whether the skilled person would have been motivated to develop a sustained-release quetiapine formulation. After noting that the skilled person would have comprised a team comprising a formulator and a clinician, and considering the expert opinions provided by the two formulators and the doctor that appeared as expert witnesses, the Court reached the conclusion that leaving aside whether or not the use of a gelling agent would have been obvious, the documents relied on by the plaintiff would not have motivated the skilled person in the first place.

All in all, the main teaching of the decision is that on the facts of this case the key question was the lack of motivation.

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