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Belgium welcomes its first enantiomer decision

Kristof Roox (Crowell & Moring) · Wednesday, May 26th, 2010

In a judgment of 11 December 2009, the Commercial Court of Antwerp invalidated the Belgian part of EP 0 663 828 of Sepracor for lack of inventive step. This patent claims the use of the active substance *levoceterizine*, an enantiomer which is used for the treatment of allergic rhinitis and asthma, and commercialized as “Xysal”. This judgment is in line with previous judgments in The Netherlands (Court of The Hague, 13 May 2009) and in France (Tribunal de Grande Instance de Paris, 6 October 2009).

The decision of the Antwerp Commercial Court is not only of interest because it is the first enantiomer-judgment in Belgium, but it also shows that Belgian courts can handle complicated patent cases in a reasonable time frame without the appointment of an expert.

The judgment is a rather straightforward application of the “problem-solution approach”. Several documents were discussed as the most recent state of the art. The Court then determined the objective technical problem: finding an active substance to treat allergic rhinitis and asthma, which is at least as effective as racemic ceterizine, while at the same time having no or fewer side effects than the racemate. Hence, the side effects were regarded as the objective technical problem. The Court found itself not in a position to judge, without technical assistance, whether the (-) enantiomer was the solution to the technical problem. The Court assumed this by way of a “fiction”. The Court then dealt with the question whether the solution to the technical problem was obvious on the priority date, given the common knowledge at that time of the person skilled in the art. The Court ruled that the person skilled in the art knew that the activity of a racemic mixture could be attributed to one of the enantiomers (while the other is inactive) and that the person skilled in the art would have examined each of the enantiomers individually. According to the Court there was a reasonable expectation of success by testing the isolated enantiomers separately. Consequently, the Court found that the Belgian part of Sepracor’s EP ‘828 lacked inventive step and annulled it, together with SPC 2009C/005. There seems to be no appeal pending.

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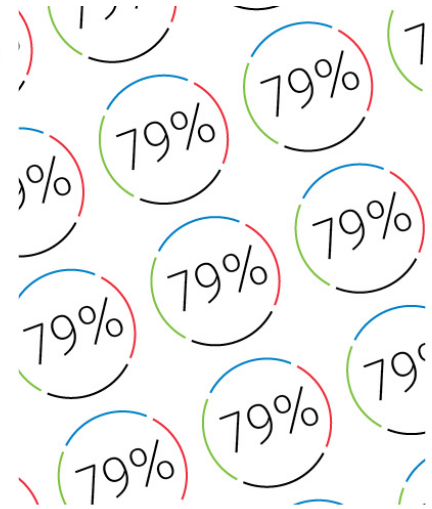
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