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Enantiomer patent case decided in Italy

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On 27 October 2010 the Court of Rome issued a decision in the Janssen – Menarini v. EG case concerning the active substance nebivolol. This is one of the few reported cases on enantiomer patents in Italy. In more detail, the basic patent inter alia disclosed an AB compound (so called compound 84) formed of a mixture of two racemates: RSSS + SRRR and RSRR + SRSS, of which the first racemate is nebivolol. The enantiomer patent concerned the s-entantiomer of nebivolol. The generic company EG sought the revocation of the enantiomer patent for lack of novelty and inventive step over the basic patent. As happens in all patent cases in Italy, the court appointed a court expert to review the technical arguments raised by the parties. He submitted a report in which he concluded that the enantiomer patent was (partially) valid, as new and inventive over the basic patent. As far as inventive step is concerned, the court expert stated that it would not be obvious for the person skilled in the art, based on compound 84, to start examining the racemate of nebivolol and further discover the specific action of the s-enantiomer of nebivolol. The court expert in particular stated that the so called “top-down” approach (i.e. the progressive division of the starting compound in the two racemates and later in the isomers thereof) was not the obvious approach, as the expert could have followed different pathways. The Court however reversed the opinion of the expert and stated that in the pharmaceutical sector, research and experimentation is routine and the activity of the person skilled in the art includes the experimentation of known compounds. Therefore, if we admit that the person skilled in the art would have inquired on the components of compound 84, it is not possible to state that that he would have hardly examined the activity of the two pairs of isomers and of their components. The limited number of the molecules forming the compound and, therefore, of the possible combinations of the same had to lead to the conclusion that a diligent skilled person would have examined them all. As regards the fact that this reasoning could be based on an hindsight bias, the Court stated that this objection should however be supported by a so called “historical evidence”, i.e. by specifically proving that the problem resolved by the patented invention (i.e. by the enantiomer patent) was already felt at the priority date but that the solution had not been found already. This was not proven, however, in the case in question.

As a quick comment, it seems that this decision was heavily influenced by the specific circumstances of the case and I would not say that a general principle can be easily drawn from this precedent as far as enantiomer patents are concerned. The Court took the view that the patent involved did not contain any indication whatsoever of the technical problem resolved by the invention and of whether the invention should represent a step forward as opposed to the state of the art. This, I am afraid, sounds like an application of the (much disputable) recent case law of the Italian Supreme Court of, which I already discussed in a previous post.

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