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Second medical use patent revoked for prior disclosure of study protocol

Daniela Ampollini (Trevisan & Cuonzo) · Wednesday, May 19th, 2010

By decision no. 6967/2009 of 14 May 2009, the IP Chamber of the Court of Milan found for the invalidity of a patent claiming the second medical use of a known pharmaceutical product for lack of inventive step. This decision is remarkable for at least two reasons.

Firstly, the Court departed from the findings of the experts it had appointed to consider the issue of validity, thus demonstrating an increasing interest by Italian judges in independently evaluating the technical merits of patent cases. As is known, considering that Italian judges have no technical background, in patent cases court advisors or experts are always appointed by the courts in order to assess the technical merit (validity and/or infringement) and issue a report to the court. During the investigations conducted by court experts, the parties extensively take part in the technical discussion, submit written comments to the court experts and attend meetings and experiments held by the same. Judges play a rather limited role in this phase and one could say that, in issuing rulings, judges may be tempted to simply follow the conclusions of the court experts although they have no obligation to do so. This decision of the Milan Court shows that, notwithstanding the appointment of experts, Italian judges like to retain the final word even on the technical merit and, in particular, on the legal implications of the factual analysis conducted by the experts on the technical issues involved.

Secondly, the decision sets a precedent on cases in which, before the priority date of the patent, information had been disclosed on the research to be conducted for the invention claimed by the patent. In the case in question, excerpts of the protocol of the clinical trials aimed at proving the second use of a known pharmaceutical product had been published in a scientific journal by the organisation carrying out the study, presumably for the purpose of attracting investments. This move, however, turned out to be fatal in terms of the validity of the patent. In particular, the Court stated that the outcome of the trials – which later became the subject matter of the patent – could not be considered surprising as opposed to the goals of the trials as described in the publication. Furthermore, according to the Court, during their investigations in the technical merit, the court experts had not identified any specific element indicating that there was a prejudice against achieving the potential results outlined in the publication of the study protocol, mainly in consideration of the fact that the primary and second use of the known product were aimed at patients having diseases of the same type. The Court in particular stated that “the protocol is nothing but the procedure followed by the inventor of the patent in suit” and that the carrying out of the same “did not have to do with the overcoming of a technical prejudice, but rather the collection of the necessary financial resources, presumably provided by the applicant company” to

the organisation which carried out the research. In conclusion, according to the Court, no value (in terms of inventive step) could be attached to the very carrying out of the experimental activity as opposed to how this experimental activity had been thought of and programmed. Nor did the Court consider that, although the first and second use of the pharmaceutical product were aimed at patients having diseases of the same type, the regulatory authorities would not allow the inclusion of the second use as a second indication of the product without the carrying out of appropriate studies. Therefore, the mere fact that the two groups of patients had diseases of the same type could per se exclude that there may be inventive step in discovering that the second (although related) disease is also cured by the known product. No doubt the prior publication of the protocol was a tremendous mistake.

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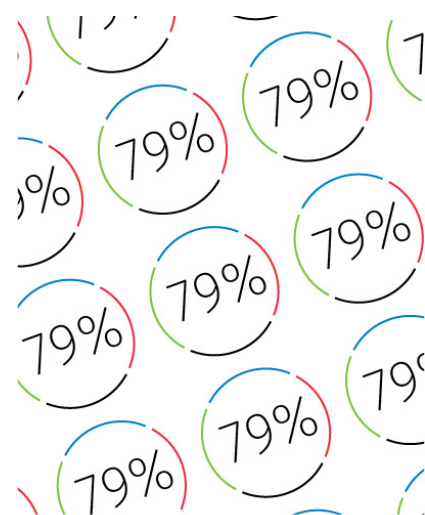
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