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Is the filing of an MA application for a generic drug an act of infringement for the Italian courts? (Part I)

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Whether patent holders marketing branded drugs may assume that the very act of filing of an MA application by generic companies result in patent infringement is one of the hottest issues at the moment being tackled by the IP Chambers of Italian district courts. The IP Chamber of the Milan Court and the IP Chamber of the Rome court have so far adopted divergent opinions.

According to the Rome Court in the preliminary proceedings between Pronova and Chiesi (decision of 23 October 2006), even when the generic drug has not been licensed yet, the filing of the MA application for the generic per se results in patent infringement as a preparatory act of marketing. This conclusion mainly derives from a provision of Italian patent law which expressly defines the filing of an MA application as an act of infringement: Art. 61(5) of the Italian IP Code (IPC) provides that

> "*Companies wishing to produce pharmaceutical specialties outside patent protection may commence the procedure for the registration of the product containing the active substance one year before the expiry of the complementary patent protection over the active substance*".

This provision is included in an article dealing with supplementary patent certificates (SPCs) and was originated by the need to mitigate the effects of the excessive length of Italian SPCs which, before the entry into force of Regulation 1768/92/EC, could extend to a maximum of 18 years in addition to patent length. The general language used in this provision, however, determines objective effects beyond the case of excessively lengthy SPCs. In stating that generic companies may file MA applications one year earlier than the expiry of the SPC protection covering the active substance, this provision also states that the same companies may not do so before as this would result in patent infringement. Further conclusions are that if there is no applicable SPC, the MA filing may only take place after the very last day of patent validity and that it is necessary to wait until after the expiry of the SPC in case the patent does not concern the "*the active substance*", e.g. it claims a novel pharmaceutical formulation.

Based on the above, the Rome Court stated that the mere filing of an MA application by the generic company when the relevant patent is still valid results in patent infringement. The Rome Court well motivated its decision also in respect of the so called "*Bolar Exception Clause*"

contained in Art. 68(1)(a) IPC, according to which the exclusive right of the patent holder does not extend

> "*to experimental activity (…) although aimed at obtaining, even in foreign countries, an authorization for the marketing of a drug and the consequent practical fulfillments including the preparation of the pharmaceutically active starting materials that are strictly necessary thereto*".

According to the Rome Court, this provision simply clarifies that the experimental activity exception extends to the experimental activity to be carried out by the generic company in order to prepare the marketing of the generic drug, but it does not to the filing with the regulatory authority of the dossier resulting therefrom. This appears as the only interpretation of Art. 68(1)(a) IPC which would not deprive abovementioned Art. 61(5) IPC of any meaning, even more considering that Art. 68(1)(a) IPC only refers to "*experimental activity*" and that there is nothing of an experimental nature in the initiation of an administrative procedure aimed at the release of a marketing authorization.

The divergent opinion of the Milan Court in the next post!

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