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Again on MA filing as a preparatory act of marketing – The Court of Turin on Art. 68 (1bis) IP Code

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In the framework of preliminary injunction proceedings instituted by AstraZeneca against the Italian subsidiary of Stada, EG S.p.A., by decision of 11 – 14 February 2011, the IP Chamber of the Court of Turin issued an interesting order concerning the application of Art. 68 (1bis) IP Code, according to which "companies intending to manufacture pharmaceutical specialties outside patent protection may commence the procedure of registration of the product containing the active ingredient one year prior to the expiry of the supplementary protection or, in absence, the patent claiming the active principle, including any applicable extension". See posts on this issue here and here, including that reporting the infringement procedure filed against Italy by the European Commission on the alleged contradiction between Art. 68 (1bis) IP Code and EU law. Firstly, the Court of Turin clarified that the provision of 68 (1bis) IP Code is an expression of the more general principle according to which activities that are preparatory in respect of the marketing of the infringing product per se result in patent infringement. Accordingly, Art. 68 (1bis) IP Code simply establishes that the filing of an MA application is a preparatory act of marketing and as such results in infringing activity. The Court also specifically clarified that Art. 68 (1bis) IP Code is not in contradiction with European law and, in particular, with the Bolar exception provided for by Art. 10 of Directive 2001/83 (which has been implemented in Italy by means of Art. 68 .1 (b) IP Code). In particular, the Court stated that the first part of Art. 10 of Directive 2001/83 is subject to the statement "without prejudice to the law relating to the protection of industrial and commercial property". Furthermore, the exception to patent rights contained in the Bolar clause encompasses only the carrying out of experimental activity and that the language "and consequential practical requirements" does not include the carrying out of the regulatory procedure. In more detail, the Court stated that the registration procedure is carried out at a stage which is much more advanced (in respect of the actual marketing of the drug) as opposed to the experimental activity, which justifies the fact that only the experimental activity (and not the carrying out of the registration procedure) be exempted by the exclusive rights deriving from the patent. This order was later revoked in appeal by order of 11 April 2011 of the appeal panel of the IP Chamber of the Court of Turin. However, the reasons of such a revocation did not concern the interpretation of Art. 68 (1bis) IP Code. This therefore remains in my view an extremely relevant precedent.

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