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

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On 18 June 2009 the IP Chamber of the Milan Court issued its official interpretation on whether the filing of an MA application for a generic drug when the patent is still in force results an act of infringement. This subject that had already been dealt with, with a different outcome, almost three years earlier by the IP Chamber of the Rome Court (see my previous post).

In the case Eli Lilly v. Ratiopharm et Al., the Milan Court stated that “the mere filing of an application for marketing authorization does not constitute infringing activity, although of a preparatory nature” as “although it is true that the filing of such an application, when the procedure is completed and after a possible experimental activity, may constitute the basis for the marketing of the drug, in the case at issue there is a prevalence of the lack of actuality of the manufacture and sale and there still is the possibility that the eventual act of marketing of the drug will not occur in practice”. The Court added that Art. 68(1)(a) IPC, on the “Bolar Exception Clause”, would seem to justify the filing of the MA application.

The latter conclusion is not convincing. Firstly, the language used by the Milan Court reveals a misunderstanding as to the time in which the “experimental activity” aimed at the MA of the generic drug takes place: obviously before, and not after, the filing of the MA application. This misunderstanding may have contributed to leading the Milan Court to finding that Art. 68 (1) (a) IPC implicitly also excepts the MA application filing. Further, it is impossible to understand how one could conclude that Art. 61(5) IPC is de facto abrogated by Art. 68(1)(a) IPC. Finally, it must be noted that in the U.S. system, where the “Bolar” principle was born, the experimental activity carried out by the generic company is admissible, while the filing of the MA application when the patent has not expired yet is by statute an act of patent infringement. Even more, based on the so called “Hatch-Waxman Act” of 1984, in case of filing of a so called “ANDA” (“Abbreviate New Drug Application”), this is immediately notified to the company marketing the ”originator”. When the patent claiming the ”originator” has not expired yet, on condition that the patent had been listed in the “Orange Book” (a registry of patents which pharmaceutical companies marketing drugs authorized by the FDA elect to enforce to protect their products), and provided that the patent holder files infringement proceedings within 45 days from ”ANDA” notification, the MA procedure is automatically stayed by the FDA for 30 months.

This appears as a good demonstration that Art. 68(1)(a) IPC does not mean that the Italian legal system contemplates a principle according to which patent infringement is excluded in case of the filing of an MA application. It in fact contemplates a contrary principle, contained in Art. 61(5)

IPC.

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