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# Kluwer Patent Blog

## Patent linkage? Infringement proceedings by the European Commission against Italy

Daniela Ampollini (Trevisan & Cuonzo) · Friday, April 8th, 2011

It has been reported by the Italian Generics Association that on 14 March 2011 the European Commission started infringement proceedings against Italy for an alleged breach of Community law related to Art. 68 (1bis) of the Italian 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”. This provision, as recently interpreted by certain case law (on which I will report shortly in another post), provides that the filing of an MA application for a generic drug, where made more than one year in advance of the expiry of the patent rights on the active substance, results in patent infringement. Within two months from the opening of the procedure the Italian Government should send its observations. It is early to make comments in this regard, also considering that to date there is no public document (or at least I haven’t found it) in which the reasons why the Commission believes that Art. 68 (1bis) IP Code may not comply with Community law are explained. At present, the only information I have on the alleged non compliance is the fact that, in the Commission’s website, the procedure is labelled as “[Patent linkage – authorisation of a medicinal product](#)”. And, as this term generally defines a case in which a regulatory authority subjects its decision to grant MAs on generic drugs to the existence and/or enforceability of patents on originators, I assume that the Commission is considering that, based on Art. 68 (1bis) IP Code, the patent system may (unduly) interfere with the administrative procedure aimed at the authorisation of the generic drug. If this is correct, however, it is difficult to see where the breach of Community law would lie. It doesn’t seem that Art. 68 (1bis) IP Code has the effect of conditioning the activity of the Italian Regulatory Authority, which seems to continue to grant MAs for generic drugs independently of the existence or non existence of patents. In contrast, it seems that Art. 68 (1bis) IP Code only concerns patent law aspects (which are by the way outside the reach of the European legislator) i.e, the fact that the filing of an MA procedure (where carried out too much in advance) results in patent infringement and, therefore, for instance justify the issue of an injunction order by the judicial authority. See another post on Art. 68 (1bis) IP Code [here](#).

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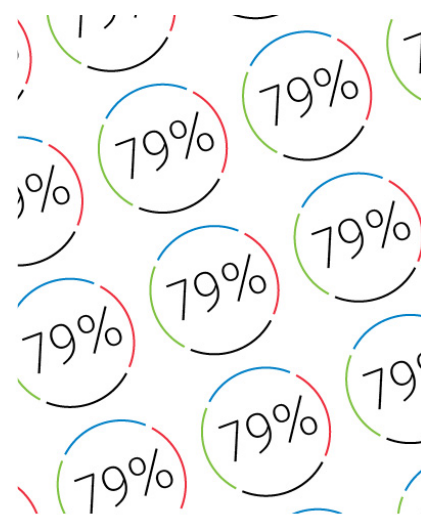
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