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New provision on mere MA application as an act of patent infringement

Daniela Ampollini (Trevisan & Cuonzo) · Wednesday, September 22nd, 2010

By [Legislative Decree no. 131 of 13 August 2010](#), which became effective on 2 September 2010, the Italian legislator passed a number of amendments to the Italian IP Code. One of these is new Art. 68 (1bis) on the statutory limitations to patent rights (which in paragraph 1 already included, and still includes, personal use, experimental use, Bolar Exception and pharmacy exception). Decree no. 131/2010 added new paragraph 1 bis which reads:

Without prejudice to paragraph 1, companies intending to manufacture pharmaceutical specialties outside the patent protection may commence the registration procedure concerning the product containing the active ingredient one year before the expiry of the supplementary protection or – in the absence of the latter – one year before the expiry of the patent on the active ingredient, also taking into consideration any possible extensions.

Those who are familiar with the debate we had in Italy on whether the filing of MA applications for generics when the originators are still covered by patent rights (see my previous posts on this subject [here](#), [here](#) and [here](#)), it will be apparent that this article can be seen as resolving the debate in favor of the reasoning behind the *Provonva v. Chiesi* case decided by the Court of Rome in 2006.

In particular, it seems that Art. 68 (1 bis) finally clarifies the scope of the Bolar Exception under Italian law, by establishing that even if GXs can carry out experiments aimed at compiling the registration dossiers even during the lifetime of the patent rights, they cannot file MA applications earlier than one year prior to the expiry of the rights.

A provision similar to new Art. 68 (1 bis) was contained already in the Italian IP Code prior to last summer's decree. This was old Art 61 (5) IP Code (which has now been cancelled). This provision established that

Companies intending manufacturing pharmaceutical specialties outside patent protection may commence the registration procedure concerning the product containing the active ingredient one year before the expiry of the supplementary protection on the active ingredient.

The interpretation of the latter was however not easy (and had given rise to the abovementioned debate). This provision was positioned within Art 61 which regulated SPCs only and which, more specifically, was aimed at coordinating the Italian SPCs which had been issued before the adoption of Regulation 349/1992/EC with the European rules, by providing for a progressive reduction of the duration of national SPCs (every passing year the SPC would be reduced by 6 months), and by expressly providing that GXs could commence the registration procedure.

These provisions had the purpose of mitigating the effects of “overly long” Italian SPCs (which could extend to 18 years after the expiry of the patent). A question was therefore posed on whether the provision of old Art. 61(5) IP Code had an impact which could go beyond the specific domain of SPCs. The Court of Rome in the Pronova v. Chiesi case had decided it did, and in particular stated that Art. 61 (5) IP Code a contrariis established the principle that the filing of an MA application is an act of infringement (being a preparatory act of marketing). Accordingly, in the absence of the SPC (as in the specific Pronova case), Art. 61 (5) IP Code would support an interpretation that the filing of the MA even one day before the expiry of the patent resulted in patent infringement.

The Milan Court, however, did not agree with this interpretation and in 2009 issued decisions in which it stated that Art. 61 (5) IP Code could not support that the mere filing of an MA application may result in patent infringement as it seemed to be inconsistent with the Bolar Exception clause. According to the Milan Court, the latter seemed to justify the filing of the MA application even before the expiry of patent rights.

New Art. 68 (1 bis) now expressly generalised the one year window to all cases of patent rights and seems therefore to say that the Rome Court interpretation prevails. How will the courts react? I foresee new posts on this topic in the next months...

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This entry was posted on Wednesday, September 22nd, 2010 at 7:00 am and is filed under ([Indirect infringement](#), [Biologics](#), [Extent of Protection](#), [Italy](#), [SPC](#))

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