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New language on patent protection in Italian MAs

Daniela Ampollini (Trevisan & Cuonzo) · Thursday, December 30th, 2010

By way of follow up of my many posts on the "intersections" between Italian patent law and the administrative procedures aimed at the authorisation of generic drugs (e.g. here, here and here), it is interesting to note another means by which the Italian Medicines Agency (AIFA) attempts to remain outside any patent dispute that may arise from the authorisation activity (especially now that new Article 68 1bis of the Italian IP Code seems to rather clearly state that the filing of a Marketing Authorisation application may per se result in patent infringement). The most recent decrees issued by the Italian authority granting Marketing Authorisations of medicinal products, contain a final article with the following wording: "Patent protection. The holder of the Marketing Authorisation of the generic drug is the sole responsible for the infringement of the industrial property rights relating to the reference medicinal product and the compliance with the provisions of patent law. The holder of the Marketing Authorisation of the generic drug is also responsible of the compliance with what established by Art. 14 (2) of legislative decree 219/2006 which forbids the inclusion into the printed material of those parts which summarise the characteristics of the reference medicinal product which refer to indications or dosages which are still covered by a patent at the time of the issue of the marketing authorisation of the drug". Until some time ago, a similar, but different, article used to be included in Marketing Authorisation decrees. It had the following language: "In order to guarantee the patent protection foreseen by Arts. 10(2), 13 and 15 of legislative decree 219/2006, the company shall not market the drug referred to in preceding article 1 until the expiry of the patent protection on the reference medicinal product". In my view, this change of wording supports the conclusion that now (i.e. after the introduction of Art. 68 1bis IP Code) it is extremely difficult to dispute that under Italian law the mere commencement of the registration procedure of a drug may amount to patent infringement. In fact, now AIFA does not just ask the MA holder to refrain from marketing the authorised drug until after the expiry of the patent, but seems to be worried of any possible liability that the authority may incur in relation to the registration procedure and therefore states that the MA holder is the sole responsible for any patent infringement which may be associated with the release of the authorisation to market.

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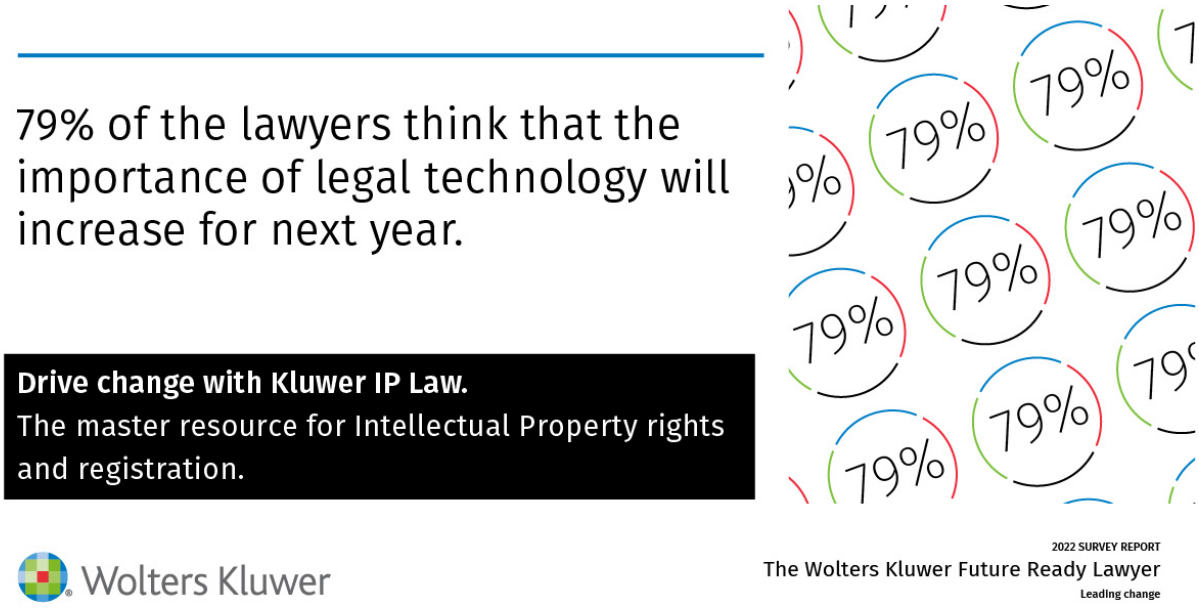

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