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# Kluwer Patent Blog

## Revisiting imminence and "Periculum in mora"

Miquel Montaña (Clifford Chance) · Thursday, September 8th, 2011

The readers will recall that one of the requirements for obtaining preliminary injunctions introduced by Directive 2004/48 (the so-called “Enforcement Directive”) is proving that there is an “imminent” threat of infringement. In cases dealing with the pharmaceutical sector, Spanish Courts have interpreted “imminent” to mean that the defendant is in an objective position to launch a product on the market at any time. For example, our Courts consider that having obtained marketing authorization and price (or being on the verge of obtaining price) creates an “imminent” risk of infringement.

Under Spanish law, another requirement for obtaining a preliminary injunction is the so-called “periculum in mora” (i.e. danger in the delay). In its judgment of 20 July 2009, the Barcelona Court of Appeal (Section 15) highlighted that the “periculum in mora” derives not only from the continuing sales that the defendant will carry out, but also from the risk that the reference product may be included in the so-called “price reference system.”

On 20 August 2011, an amendment of Law 29/2006 (the Medicines Law) came into force that has caused these requirements to be revisited. Before this amendment, the Ministry of Health was not entitled to create a “group” of active ingredients for the purpose of applying the “price reference system” until the first generic had been launched. However, the amendment now allows the Ministry to create a “group” as soon as the price of the first generic has been set, even if that generic has not been launched yet. Therefore, the “periculum in mora” now derives not only from the risk that the defendant might launch its product, but also from the risk that it might obtain price, which would automatically prompt the creation of the “group”. In this regard, in its judgment of 20 January 2011, the Barcelona Court of Appeal (Section 15) found that obtaining price well before the expiry date of the patent that protects the reference product may constitute an act of unfair competition.

All in all, the amendments introduced by the Spanish government while the rest of the country was on holidays have caused those who are back to school to have to revisit imminence and “periculum in mora”.

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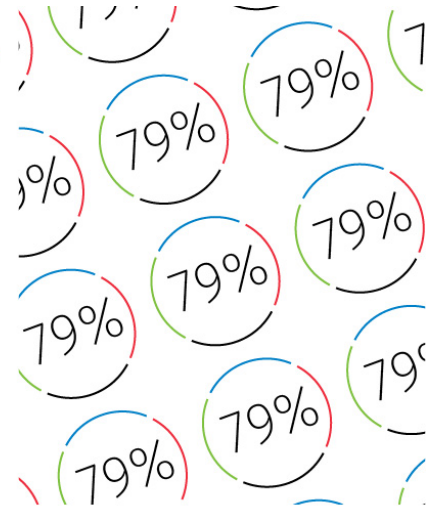
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