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# Kluwer Patent Blog

## How useful are undertakings not to launch?

Miquel Montaña (Clifford Chance) · Thursday, August 25th, 2011

One of the possible courses of action open to patentees when they suspect that a competitor may be preparing the launch of a product that may infringe a patent in force is to send a warning letter. If the response is evasive, this would normally help the patentee to prove that there is an “imminent” threat of infringement. What if the response is in the form of an undertaking not to launch? Would this prevent the patentee from applying for a preliminary injunction?

On 29 December of 2009, the Commercial Court Number 5 of Barcelona handed down a judgment ordering a preliminary injunction against Mylan Pharmaceuticals S.L. (“Mylan”) after noting that it had obtained market authorization and price to market a generic of donepezil. According to the Court, the fact that Mylan had obtained price more than 3 years before the expiry date of the patentee’s SPC (which would cause the marketing authorization to expire) amounted to an “imminent” threat of infringement and to an act of “unfair competition”, since it would cause the price of the original medicament to be reduced even if the generic was not ultimately marketed. For the readers’ benefit, it should be clarified that according to the Spanish Ministry of Health, to include an original medicament in the “price reference system” it is sufficient for one generic to have obtained price, even if the generic has not been launched as yet.

In its judgment of 20 January 2011, the Court of Appeal of Barcelona (Section 15) confirmed the preliminary injunction ordered but reversed the finding of the Court of First Instance based on the “imminent” threat of infringement. According to the Court of Appeal, “on other occasions on which we have noticed the imminence of infringement, there was not such a clear statement from the defendant not to carry out the marketing acts”. The Court of Appeal added that “it is not plausible to the Court that the defendant, after the statements made [...] assuring that there will be no commercialisation until the SPC expires, would defraud this expectation and start commercialisation. If it were to do so, in addition to the fact that it would be possible to order an urgent and “ex parte” preliminary injunction for the purpose of ordering the cessation of the infringement, the behaviour denounced would be marked by clear temerity and bad faith”.

All in all, this recent judgment appears to suggest that if an undertaking is clear enough it may be as good as a preliminary injunction.

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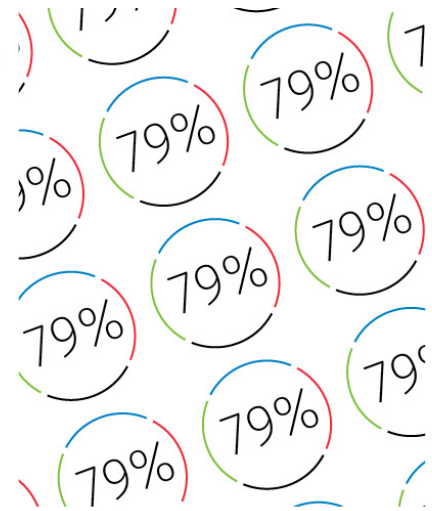
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