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Does obtaining marketing authorization and price to market a medicament constitute sufficient indicia of "imminent" infringement?

Miquel Montaña (Clifford Chance) · Monday, May 10th, 2010

One of the new question marks introduced by [Directive 2004/48](#) (the so-called "Enforcement Directive") is what amount of indicia is required to prove that an act of infringement is "imminent" for the purposes of obtaining a preliminary injunction aimed at prohibiting such act. Although the declared goal of the Enforcement Directive was to strengthen the protection of intellectual property right holders, as far as Spain is concerned, the new "imminent" threat of infringement requirement introduced by the Directive has worsened this protection, since it has introduced a new requirement to the three conditions traditionally required to obtain preliminary injunctions (likelihood of success in the main proceedings, danger in the delay, and working the patent within a WTO member state). Before Directive 2004/48 was implemented through Law 19/2006, a Spanish Judge would normally order a preliminary injunction if these three conditions were fulfilled, without considering how imminent or how distant the alleged act of infringement was.

In the context of medicaments, a question that has arisen is whether obtaining marketing authorization and price to market a pharmaceutical product constitute sufficient indicia to show that an act of patent infringement is "imminent". So far, the answer to this question has depended on the overall circumstances of the case. For example, when the marketing authorization has been obtained three years before patent expiry, Spanish Judges have considered that this proves that the threat of infringement is "imminent". This is because if the product is not launched within three years, the marketing authorization would expire (known as the "sunset clause"). Also, if there has been an exchange of correspondence prior to the litigation and the defendant has not undertaken not to launch, that would be another indicium that a Judge would take into account to consider that the act of infringement may be "imminent". On the contrary, if a marketing authorization is obtained shortly before the date when the patent is due to expire, in the absence of other means of evidence this would not be sufficient to prove that the new "imminent" threat of infringement requirement is met.

The judgment of 9 June 2008 from Commercial Court number 4 of Barcelona, which was later confirmed by the Court of Appeal of Barcelona through a judgment of 20 July 2009, is a good example of how our Commercial Courts are interpreting the "imminent" threat of infringement requirement.

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