Interim protection of marketing protection periods in commercial courts

Order of the Provincial Court of Barcelona, Section 15 (Civil), No. 56/2025, of 9 April 2025

In this order, the Provincial Court of Barcelona confirms the preliminary injunctions granted by the Commercial Court No. 10 of Barcelona prohibiting the marketing of a generic medicinal product prior to the expiry of the marketing protection period of the reference medicinal product.

Background

European and Spanish regulations are clear on this point: generic medicinal products and biosimilars, which have obtained their marketing authorisation based on the data of a reference medicinal product, cannot be marketed until the expiry of the reference product's marketing protection period.

What options are available to the marketing authorisation holder (MAH) of the reference medicinal product if a generic or biosimilar MAH breaches this exclusivity period and initiates marketing prematurely?

In the case examined by the Provincial Court of Barcelona, the MAH of the reference medicinal product successfully secured protection of its rights through a preliminary injunction granted under the Law on Unfair Competition.

Fumus boni iuris y periculum in mora

When an action is brought to safeguard the marketing protection period, it is logical for the claimant to request, as a preliminary injunction, the suspension of the marketing of the generic or biosimilar medicinal product. As is well known, the claimant must demonstrate the existence of a prima facie case (fumus boni iuris) and the risk of irreparable harm caused by delay (periculum in mora).

In the case at hand, the Provincial Court upholds the order granting the preliminary injunction requested, and, in doing so, provided sound reasoning regarding both the requirements for such interim relief and the rules governing the marketing of generics and biosimilars

With respect to the existence of a prima facie case, the Provincial Court points out that the claimant's right to the marketing protection period - during the so-called "+1" year - was expressly recognised by a European Commission decision. As the Court highlighted, the validity of that decision was not in question, particularly after the General Court of the European Union repeatedly refused to provisionally suspend its enforceability.

As to the risk of irreparable harm, the Court emphasised that when a generic medicinal product is placed on the market before the expiry of the marketing protection period, the only effective way to prevent irreparable damage is to order the immediate cessation of such marketing activity.

In this regard, the Court confirms that the applicable rules on marketing protection establish, in favour of the MAH of the reference medicinal product, an exclusive right to market its product free from generic competition until the protection period expires. Denying the request for a preliminary injunction would entail the irreversible loss of this exclusivity, which, once breached, cannot be restored.

Furthermore, the Provincial Court emphasises that the possibility of obtaining compensation can in no way constitute an obstacle to the granting of a preliminary injunction. First, because the loss of marketing exclusivity, in itself, constitutes irreparable harm; and second, because such loss also entails economic damage that may be difficult to quantify.

The Provincial Court further notes that, to justify the existence of irreparable harm, it is sufficient to show that compensation would be unlikely to fully redress the actual harm suffered.

On the rules concerning the marketing of generic medicinal products

The order under analysis also clarifies the regime applicable to the marketing of generic medicinal products, specifically regarding the 8-year data protection period and the subsequent 2+1-year marketing protection period.

Undoubtedly, this ruling constitutes a valuable judicial precedent and is one worth keeping in mind for future cases on these issues.

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