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Pre-launch activities by generic companies: patent law and unfair competition

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The Spanish courts have previously dealt with the question of whether specific pre-launch activities carried out by generic companies in the context of marketing authorisations and price approval should be regarded as acts of patent infringement. However, there is still discussion as to whether some of these activities prove the risk of infringement of an existing patent, and whether the patentee may prevent such activities through the prohibition action established under the Patent Act. Furthermore, the impact of these acts by generic companies on innovators has also been considered in light of the provisions of the Unfair Competition Act. In a decision of 22nd January 2013 the Barcelona Court of Appeal has ruled on these matters.

Background

The defendant had obtained marketing authorisations for the commercialisation of its drugs more than three years before the expiry date of the supplementary protection certificate (SPC) protecting the relevant active ingredient. The defendant not only obtained these marketing authorisations, but also applied for and obtained price fixation for its drugs and requested their inclusion in the National Health System.

In its reply to the cease-and-desist letter sent by the plaintiffs, the defendant expressed its intention of not launching its drugs before the expiry or termination of the SPC. However, the plaintiffs did not regard this express intention as a clear undertaking and applied for a preliminary injunction in order to prevent:

- The imminent infringement of the SPC.
- The effect of the interference by the defendant, given that the inclusion of the generic drugs in the National Health System would inevitably cause a drop in the price of the innovator drugs by virtue of the Reference Price System.

First instance decision

The Barcelona Commercial Court No 5 granted preliminary injunctions against the defendant on the basis of patent infringement and unfair competition. The court applied the same consideration to its judgment rendered on the merits of the case.

Patent infringement

In relation to patent infringement, the Barcelona Commercial Court No 5 considered that the acts carried out by the defendant proved an imminent infringement of the SPC, which could be prevented by the patentee through the prohibition action. In summary, the court estimated the following circumstances as a clear indicator of the likelihood of infringement of the patent:

- Anticipated application for marketing authorisations - the defendant was granted the marketing authorisations more than three years before the expiry of the SPC. Pursuant to the sunset clause, the marketing authorisation holder must market the drugs within a period of three years from the granting date. This means that the defendant should have launched the drugs before the expiry of the SPC to avoid the expiry of the marketing authorisations. According to the court, the defendant did not provide any real justification to this unusual anticipation.
- Marketing authorisations not suspended in the Spanish Medical Agency database - among other duties, the marketing authorisation holder is required to notify the Spanish Medical Agency every October whether it intends to market the drug in the following year. If the marketing authorisation holder does not express its intention of marketing the drug, the Spanish Medical Agency will record the marketing authorisations as suspended. In the present case, the defendant's marketing authorisations appeared as marketed, and not as suspended, which means that the defendant informed the Spanish Medical Agency of its intention to market the drugs.
- Characteristics of the information provided by the defendant to the Spanish Pricing Authority - in accordance with extensive case law on this issue, the court considered that if the defendant was able to provide all relevant information for the approval of the drug prices (three years prior to the expiry of the SPC) to the Pricing Authority, it was because it had the intention of launching the drugs before expiry. In the court's opinion, this information can be determined only after having carried out specific marketing, financial and economic studies near the launch of the drug.
- Non-suspension of the price approval process by the defendant - the court considered that the defendant was not required by law to conclude the price approval process and that it could have

requested its suspension.

Unfair competition

According to existing Pricing Authority practice when the litigation was initiated, the creation of a reference group for an active ingredient must depend on whether a generic drug containing that active ingredient has been included in the National Health System. For this purpose, it was irrelevant whether such generic drug was being marketed effectively. The creation of a reference group would lead to the approval of a reference price for all of the drugs included in the group. Thus, all drugs with the same active ingredient and the same method of administration would be included in the reference group and the reference price would apply to all of them. The reference price was set taking into consideration the prices established for all the drugs included in the group. Since the prices of generic drugs are considerably lower than the prices of the innovator drugs, the creation of a reference group and the implementation of the reference price would cause a dramatic drop in the market price of the innovator drug.

In light of this scenario, the anticipated conclusion by a generic company of all the steps before the launch of the drug plays an important role. Even if the generic company does not plan to market its drug before the expiry of the patent rights, it may cause severe damage to competitors. Thus, the issue to be addressed is whether such behaviour by the generic company should be regarded as an act of unfair competition and, more specifically, whether it meets the requirements to be considered as an act of interference that can be prevented under Article 4 of the Unfair Competition Act.

The courts considered this issue for the first time in this litigation. In its decisions in both the preliminary injunction proceedings and the proceedings on the merits of the case, Barcelona Commercial Court No 5 concluded that the defendant's behaviour was not justified by objective, competitive reasons. Furthermore, the court estimated that in view of the harmful effects on the plaintiff of the actions carried out by the defendant, the defendant had interfered in the plaintiff's commercial exclusivity.

Barcelona Court of Appeal decision

The 22nd January 2013 decision of the Barcelona Court of Appeal confirmed that court's 20th January 2011 ruling in the preliminary injunction proceedings. The Barcelona Court of Appeal essentially agreed with the opinion of the first instance court, but did not grant relief under the Patent Law due to specific subjective factors.

Patent infringement

Of the four objective indicators that the first instance court considered to allow the claim under the Patent Law, the Barcelona Court of Appeal agreed with all except one (that the marketing authorisations did not appear as suspended in the Spanish Medical Agency database). The appeal court did not consider it to have been proven sufficiently that the defendant had filed a declaration of its intention to market its drug with the Spanish Medical Agency before expiry of the patent rights.

However, the appeal court considered that these objective indicators had to be considered alongside the subjective indicators of the case. According to the appeal court, the defendant had expressed its intention of not launching its drugs before the expiry of the plaintiff's SPC in:

- Its reply to the cease-and-desist letter sent by the plaintiff.
- A letter sent to the Directorate General for Pharmacy and Healthcare Products before obtaining drug prices.
- The defence brief filed in the proceedings, in which the defendant did not question that its drugs fell within the scope of protection of the SPC.

Thus, the Barcelona Court of Appeal held that under these circumstances it had to be concluded that the defendant would not launch its products while the SPC was still in force because the defendant was perfectly aware that any breach of this undertaking would result in the plaintiff applying for an *ex parte* injunction that would automatically be granted by the courts.

The appeal court's decision is somewhat inconsistent with its previous case law on the assessment of the imminence of infringement. Although the previous cases had different facts, in its decisions of 17th and 28th June 2010 the Barcelona Court of Appeal clearly put the objective indicators of infringement ahead of the subjective indicators. In its 17th June 2010 decision the appeal court stated that:

"*[W]e agree that the assessment of the imminence of infringement must be based on objective indicators, because otherwise the preliminary relief would be left at the mercy of intentional statements from the potential infringer, just by stating that it does not have the intention of marketing the drug even though [it] has obtained*

the [marketing authorisations] for doing so."

Unfair competition

In relation to the acts of interference taken into consideration by the first instance court, the Barcelona Court of Appeal maintained the same criteria as in the appealed decision: the defendant's behaviour lacked any objective justification from a competitive point of view, and therefore the plaintiff was entitled to prevent the effects of the act of unfair competition. According to the appeal court, the Unfair Competition Act is in this case complementary to the provisions of the Patent Act. Therefore, even if the risk of infringement of the SPC is disregarded by the court, the maintenance of the commercial exclusivity of the plaintiffs must be protected by the Unfair Competition Act.

The appeal court primarily put the absence of an objective justification applicable to the acts carried out by the generic company down to the anticipation with which the defendant concluded all the steps before the launch of its drug in relation to the expiry date of the exclusive right. The defendant was aware that by applying for price fixation and inclusion of the drug in the National Health System, the plaintiff would suffer a price drop, and the defendant failed to put forward good-faith arguments to justify its behaviour.

This criterion was applied by the Barcelona Court of Appeal in its 20th January 2011 decision on the preliminary injunction, and was also applied by Barcelona Commercial Court No 8 in a decision of 18th April 2012.

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