



Ignacio Pontijas

Effectiveness of protective briefs in pharmaceutical patent matters

GRAU & ANGULO
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Introduction

As a general rule, defendants in Spain must be heard before a preliminary injunction request against them can be upheld. Preliminary injunctions can therefore be granted *ex parte* only in exceptional cases – namely, in cases of urgency or if the hearing could jeopardise the preliminary injunction's aim.

However, in pharmaceutical patent cases, plaintiffs often request *ex parte* preliminary injunctions and, for some years, many such requests were upheld despite their exceptional nature.

Until recently, it was relatively common for the patent courts to grant preliminary injunctions *ex parte*. However, in many cases, these same courts would – after hearing the defendants – revoke the preliminary injunction for being groundless. This is precisely what happened in the 2017 cases involving:

- valsartan and amlodipine (Exforge);
- oxycodone and naloxone (Targin);
- tenofovir and emtricitabine (Truvada); and
- NuvaRing.

Protective briefs

In light of this situation, the new Patents Act (which came into force in April 2017) introduced the possibility of filing protective briefs in cases where it is foreseeable that an *ex parte* preliminary injunction will be requested (the Barcelona patent courts had previously started admitting such briefs despite the fact that they were not expressly contemplated in the law). The main purpose of a protective brief is to avoid a preliminary injunction being granted *ex parte*. To this end, the future defendant can appear before the court, justify that there is no extreme

urgency for the injunction and outline its arguments on the merits of the case.

In order to better understand the usefulness of protective briefs, this article examines some recent cases in which they have proved very effective for the defendants.

Recent cases

Rituximab case

In the rituximab case (MabThera), Celltrion and Kern Pharma filed a protective brief to mitigate the risk of Biogen, Roche and Genentech seeking an *ex parte* preliminary injunction against them for the infringement of two patents, after having received warning letters from the companies. In the protective brief, Celltrion and Kern Pharma argued that there was no extreme urgency for the injunction and outlined the reasons why the patents in question were clearly invalid. The protective brief was admitted by Barcelona Commercial Court Number 4, whose order was formally served on the pre-plaintiffs.

Ultimately, Biogen, Roche and Genentech did not request a preliminary injunction. Instead, they simply filed a main action for infringement of the patents.

Ezetimibe and simvastatine case

In the ezetimibe and simvastatine case (Inegy), Barcelona Commercial Court Number 5 refused to grant the preliminary injunction which MSD had requested *ex parte* against a number of generics and decided to schedule a hearing to hear the defendants. In its 17 April 2018 order and based on the protective brief previously filed by the defendants, the court concluded that MSD could and should have filed its preliminary injunction request much earlier than it did, as the defendants had informed MSD well in advance about the launch of their generic drugs.

After the hearing, the court definitively dismissed MSD's preliminary injunction request (due to the *prima facie* invalidity of the asserted supplementary protection certificate (SPC)).

Darunavir case

In the darunavir case (Prezista), Searle and Janssen requested an *ex parte* preliminary injunction against Sandoz for alleged SPC infringement. Sandoz had previously filed a protective brief alerting the court that Searle and Janssen were deliberately delaying their request so as to artificially generate an alleged urgency and obtain the preliminary injunction *ex parte*.

Barcelona Commercial Court Number 1 refused to prosecute the preliminary injunction request *ex parte* and summoned the parties to a hearing. In her decision of 6 February 2019, the judge explained that the protective brief had been key in informing the court of the situation and observed that the plaintiff was to blame for the delay in requesting the preliminary injunction when it learned of the defendant's marketing intention.

Following this decision, Searle and Janssen withdrew their preliminary injunction request. As such, the hearing did not take place.

Comment

The above precedents show that protective briefs constitute a new tool that can, in certain cases, reduce or even eliminate the risk of an *ex parte* preliminary injunction and the inconveniences associated therewith. Of course, in practice, whether it is advisable to file a protective brief must be assessed on a case-by-case basis, as this will depend on the specific circumstances of the case at hand.

For further information on this topic please contact Ignacio Pontijas at Grau & Angulo by

telephone (+34 91 353 36 77) or email (i.pontijas@ga-ip.com). The Grau & Angulo website can be accessed at www.ga-ip.com.

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