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PRELIMINARY INJUNCTIONS, IMMINENCE AND UNDERTAKINGS: ONE STEP UP AND TWO STEPS BACK

Miquel Montaña (Clifford Chance) · Thursday, December 27th, 2012

“It’s the same thing night on night / Who’s wrong baby who’s right / Another fight and I slam the door on / Another battle in our dirty little war / When I look at myself I don’t see the man I wanted to be / Somewhere along the line I slipped off the track / I’m caught movin’ one step up and two steps back.”

The lyrics of “One Step Up”, by Bruce Springsteen, very nicely illustrate the effect that Directive 2004/48 (the so-called “Enforcement Directive”) had on the legal protection of intellectual property owners in Spain. It caused them to go one step up and two steps back, as shown by the Decision of 13 December of 2012 from Commercial Court number 1 of Barcelona. As the reader will see, whereas the Enforcement Directive was meant to take intellectual property owners one step up, the “imminence” requirement introduced as a prerequisite to obtain a preliminary injunction sent them two steps back.

This very recent interesting decision has discussed the interplay between the indicia of imminent threats of infringement and an undertaking not to carry out infringing acts imminently. The background of the case may be summarized as follows:

Company X owns a patent and a Supplementary Protection Certificate (“SPC”) with “Swiss-type” claims that expires on 27 May 2019. At the beginning of July 2012, the Spanish Medicines Agency published in a data base only accessible to pharmaceutical laboratories that company Y had obtained a marketing authorization to market a generic for the same use than the use protected in said patent. The patent owner sent two “cease & desist” letters to company Y, which were not responded by the latter. Against this background, during the last week of July, the patent owner filed an application for an “ex parte” preliminary injunction against company Y alleging the following indicia of “imminent” infringement and unfair competition acts: (i) the date when the SPC was due to expire (27 May 2019); (ii) the fact that the marketing authorisation would expire within 3 years, that is, well before the expiry date of the SPC; (iii) the fact that the marketing authorisation was granted following the “mutual recognition” of a marketing authorisation granted by another European Union member state (and not the other way around); (iv) the fact that company Y never sent a response to the warning letters received.

On 1 August 2012, Commercial Court number 1 of Barcelona ordered an “ex parte” preliminary injunction, which included an order not to make a price offer to the Ministry of

Health. It should be noted, in passing, that under Spanish law setting the price for the first generic has devastating consequences for the owner of the medicament of reference. Once the price of the first generic has been fixed, it has two options: reduce its own price (with irreversible effects) or get out of the market. Hence the importance of these types of provisional measures.

After the summer, company Y filed a writ of opposition against the decision ordering the “ex parte” preliminary injunction, based on several arguments from which the following may be highlighted. First, it filed data from the Spanish Medicines Agency according to which the marketing authorisation would have been granted on 2 August 2012 and not at the beginning of July. In addition, it filed documents showing that on 10 September 2012 it had asked the Ministry of Health not to include its product on the list of products financed by the Spanish Social Security System and that on 11 October 2012 the Ministry of Health had excluded the product from the list. Third, it argued that obtaining a marketing authorisation for a generic is a legal activity exempted from patent infringement by the “Bolar” clause introduced by Directive 2004/27.

The Court then called the parties to a hearing. At the hearing, the patent owner alleged that the preliminary injunction should be confirmed because in its writ of opposition the defendant had not accepted an undertaking not to launch while the SPC was in force. In addition, it argued that the fact that the defendant’s product had been excluded from the list of products financed by the Spanish Social Security System was insufficient, as the product could be put on the list again within a few weeks. For its part, the defendant alleged that obtaining a marketing authorisation is legal and that it would not launch its product onto the market for the time being.

In its Decision of 13 December 2012, the Court highlighted that there were several indicia showing that there was an imminent threat of infringement (the expiry date of the SPC, the date when the marketing authorisation would expire, etc.). However, the Court considered that the undertaking not to launch expressed by the defendant at the hearing of the preliminary injunction was key. According to the Court, in view of the good faith principle that must govern the process, the undertaking assumed by the defendant blurs any risk of imminent infringement. The Court hinted that should the defendant failed to honour this undertaking, the patent owner should be able to go to Court again and obtain a preliminary injunction “ex parte” in a very short timeframe. All in all, the Court lifted the preliminary injunction. Finally, although when a preliminary injunction ordered “ex parte” is lifted, the applicant is normally ordered to bear the costs of the proceedings, in this case the Court did not award costs in view of the serious doubts of law regarding the nature and scope of the undertaking not to launch and the circumstances that led the defendant to request the suspension of its marketing authorisation.

This case again illustrates that the “imminence” requirement introduced by Directive 2004/48 worsened the legal protection of intellectual property owners, which is at odds with the purpose and goals of the Directive. Before the Spanish Patent Act was amended to introduce this new requirement, a patent owner would not have been required to go through the cumbersome and costly process of applying for a preliminary injunction twice in the circumstances of a case like this. There is no doubt that having to spend the time and costs required for going to Court again after having already obtained a preliminary injunction is going one step up and two steps back.

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