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Recent judgment sheds further light on the "imminence" imbroglio

Miquel Montaña (Clifford Chance) · Friday, February 6th, 2015

Rather ironically, Directive 2004/48/EC (the “Enforcement Directive”), which was meant to enhance the protection of intellectual property rights throughout the European Union (“EU”), had just the opposite effect, at least in one aspect. As the readers know well, the Directive requires the applicant of a preliminary injunction to prove that an act of infringement is “imminent.” The introduction of this “imminency” requirement, which was not a condition for granting a preliminary injunction in some EU member states, has since then caused national courts to struggle to try to untangle the exact boundaries of this requirement.

In a post published on 2 July 2013, we discussed a Ruling handed down on 10 June 2013 by the Barcelona Court of Appeal (Section 15), stating that it was the “penultimate word on imminence”. On 20 January 2015, Barcelona Commercial Court number 1 handed down a judgment in the corresponding main proceedings, where it has made the – for the time being – ultimate contribution to the saga of decisions on “imminence.”

This judgment has upheld an infringement action filed by a pharmaceutical company against a manufacturer of generic medicaments that had obtained an authorisation to market a generic falling within the scope of a patent owned by the former.

In the judgment, the Court first draws the contours of “imminence” as depicted in the above-mentioned Ruling handed down by the Barcelona Court of Appeal. According to such Ruling, “imminence” must be “clear” (i.e. “evident” or “easily perceived”), requiring a “qualified probability” that infringement will take place, “proximity in time” (proximity which depends on the circumstances of each case but which the first instance Court finds should not go beyond “a few” months), and “conclusive indicia” on the risk of infringement.

The judgment, after examining the facts of the case at hand, highlights that, as a general rule, obtaining a marketing authorisation well in advance of patent expiry is not a sufficient indication of “imminence” taken alone, and must be interpreted in the wider context of all the indicia alleged.

In this case, the indicia which the Court has found relevant and, when taken together, conclusive, to determine “imminence” of infringement are:

1. The fact that the defendant has not made a formal undertaking not to launch. Leaving aside the fact that the defendant did not reply to the warning letters sent by the patentee before the proceedings began, the Court gives special relevance to the fact that the defendant did not undertake not to launch when it filed its opposition against the preliminary injunctions, or even during subsequent stages of the proceedings.
2. The fact that the marketing authorisation for the infringing product was obtained almost seven years before the patent’s expiry, and the defendant did not offer a “specific explanation” as to why

it had applied for an authorisation so far in advance.

3. The possible application of the “sunset clause”, according to which the marketing authorisation would expire within three years unless the defendant launched its product. The Court finds that the most reasonable conclusion is that the mere “threat” of applying this clause would prevent an entity from applying for a marketing authorisation if it intends to launch in more than three years’ time.

4. The Court addresses the potential importance of offering a price as a sign of “imminence”, but finds that, due to the prohibition against making a price offer set out in the preliminary injunctions Ruling, in this case, it is not possible to ascertain what the defendant’s actions would have been in this regard, if such injunctions had not existed.

Once more, this judgment further confirms that “imminence” of infringement has to be analysed on a case-by-case basis, taking into account the specific combination of indicia existing in each case (such as, for example, the defendant’s willingness to undertake not to launch, the remaining life of the patent in suit, or the possibility of the marketing authorization being subject to the “sunset clause”).

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