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How much is needed to find a threat of patent infringement? A respectful dissent

Miquel Montaña (Clifford Chance) · Thursday, May 27th, 2021

As any aficionado of American legal history will be well aware, Judge Holmes, the third most cited American legal scholar of the 20th century, was nicknamed “*the Great Dissenter*.” This was a tribute to the 55 dissenting opinions that he wrote during his 29 years serving at the U.S. Supreme Court. Interestingly, over the years many of his dissenting opinions would end up paving the way for future policies.

A recent judgment of 26 April 2021 from the Barcelona Court of Appeal (Section 15) illustrates the usefulness of dissenting opinions as food for further thought. The facts of the case relevant to this blog may be summarized as follows:

A Spanish company filed a revocation action against patent EP 888 289 (“EP ‘289”) and its corresponding SPC, which protects lacosamide, an antiepileptic drug. The patent owner filed a statement of defense together with a counterclaim, in which it requested the Court to prohibit that company from launching its product into the market before the SPC expired. In a nutshell, it alleged that the activities carried out by that company constituted a “threat of infringement.” Specifically, it mentioned the following acts: a) obtaining a marketing authorization many years ahead of the expiry date of the SPC; b) obtaining a price also years ahead of the expiry date of the SPC; c) having filed a revocation action; d) having failed to undertake to wait for the expiry date of the SPC despite having received three warning letters; and e) all the other companies that had obtained marketing authorization *and price* had undertaken not to launch while the SPC was in force.

The Court of First Instance, in a judgment of 14 April 2020, dismissed the revocation action. It also dismissed the counterclaim, on the grounds that actions against “threats of infringement” would have no legal basis in Spanish law.

One of the most interesting aspects of the judgment of the Barcelona Court of Appeal (Section 15) discussed in this blog is that it has implicitly corrected this finding. This is very clear in paragraph 75, where the Court reaches the conclusion that it cannot be considered that having obtained marketing authorization “[...] constitutes, as such, a threat of infringement.” So, unlike the Court of First Instance, the Court of Appeal admitted the right to act against activities that constitute “a threat of infringement.” However, after considering the specific facts of the case at hand, it concluded that no threat of infringement had been demonstrated in the case before the bench.

To put this finding in context, some clarifications are warranted. Under Spanish law, launching a drug onto the market requires having completed three steps: a) obtaining marketing approval; b) obtaining a price; and c) making the so-called “effective marketing declaration.” This last step is a formal notification to the Spanish Medicines Agency that must be made approximately one month before launch. According to the relevant regulations, a company wishing to launch on, say, 1 June, must make the “effective marketing declaration” within the first 15 days of the previous month (i.e. before 15 May).

To cut a long story short, in its judgment of 26 April 2021, the Court of Appeal seems to have considered that for a “threat of infringement” to exist this “effective marketing declaration” must have been made. This is very clear in paragraphs 69–74, where the Court tried to distinguish this case from its judgment of 22 January 2013 (Donepezil), in which it reached a different conclusion. In particular, in paragraph 71, the Court noted that the regulatory context has changed since that case. Whereas when the Donepezil case was decided the factor that triggered the creation of the so-called “price reference system,” and the ensuing damages for the patent owner, was obtaining price, according to the new regulations approved since then, the triggering factor is making the “effective marketing declaration.” In our respectful opinion, this seems to be more relevant for determining the possible economic consequences of a “threat of infringement” than for establishing whether or not there has been a “threat of infringement” in the first place, which is a different question. Also, the Court found that having filed a revocation action is not an indication of a “threat of infringement” but rather the contrary. This conclusion seems to be based on the belief that a company that has filed a revocation action will not launch until it has obtained a judgment revoking the patent. But this belief is at odds with reality, as shown by the Olanzapine case, where some companies that had filed a revocation action against the patent protecting that product tried to launch before the revocation action was resolved. Interestingly, even the very same company that had filed the revocation action against the Lacosamide patent in the case discussed in this blog tried to launch generics of Olanzapine without waiting for the outcome of the revocation action.

The launch was prevented by several preliminary injunctions ordered by Barcelona Commercial Court number 1, which were later confirmed by the Barcelona Court of Appeal (Section 15). More recently, another company that had filed a revocation action against the patent protecting Pemetrexed tried to launch without waiting even for a first instance judgment. The launch was aborted due to a preliminary injunction ordered *ex parte* by Barcelona Commercial Court number 4 on 2 September 2019. These examples illustrate that companies eager to earn multimillion profits by trying to launch at risk are not following the cautious path expected by the Court in the judgment discussed in this blog.

The point is, of course, debatable, as illustrated by the dissenting opinion written by one of the members of the Court of Appeal in this case. The same member also noted that the regulatory context has changed since the judgment of 22 January 2013 (Donepezil). In particular, he mentioned the entry into force of the new Patent Act on 1 April 2017, which introduced, in article 71.1, the right of the patent owner to request the cessation of the acts that infringe its right “*or their prohibition if they have not yet taken place.*” This latter right had to be introduced to comply with article 9.1 of the Enforcement Directive (Directive 2004/48/EC), which, in turn, had introduced this right to comply with article 50 of TRIPS. The question at issue is how far the preparations to infringe must have reached to allow the patent owner to obtain a judgment prohibiting infringement.

The judgment did not cite or interpret the contours of the “prohibition action” introduced in article 71.1 of the Patent Act. The dissenting opinion, however, made a contribution to this debate in

paragraph 3, where it stated the following: “*The purpose of the prohibition action is to restrain future infringement that has not yet taken place when there are serious reasons to believe that infringement is probable.*” In paragraph 6, it added: “*Therefore, for the prohibition action to succeed, the plaintiff must show rational evidence of the imminence of the acts of infringement.*” The latter sentence is, of course, also debatable, since, as the dissenting opinion explains in paragraphs 8 and 9, “imminence” is a requirement for preliminary injunctions aimed at prohibiting acts of infringement that, to be prohibited, the legislature requires be “imminent.” No such requirement was included in article 71.1 for prohibition actions in the main proceedings. This may be interpreted as a sign that the legislature wanted the test for prohibition actions to be less stringent than the strict “imminence” test required for preliminary injunctions. In this regard, the judgment of 22 January 2013, although published before the Patent Act was amended, appears better tailored to the text and spirit of article 71.1 of the new Patent Act.

All in all, the differing views expressed by the majority of the Court and the dissenting opinion in this case illustrate that, as used to be the case with Judge Holmes’s dissenting opinions, this debate is here to stay.

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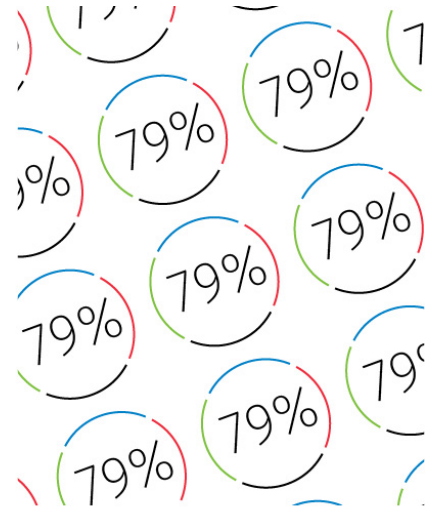
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