## **Kluwer Patent Blog**

## The UK Supreme Court on pemetrexed: judicial colonialism or a step towards harmonization?

Miquel Montañá (Clifford Chance) · Monday, July 20th, 2020

On 9 June 2020 Barcelona Commercial Court no. 4 issued a decision rejecting the opposition filed by a company (the "Defendant") against a decision of 2 September 2019 from the same Court that had ordered an "*ex parte*" preliminary injunction preventing the Defendant from marketing pemetrexed diarginine in Spain. The background of the case can be summarized as follows:

In 2016 the Defendant obtained a marketing authorization ("MA") to commercialize pemetrexed disodium generics in Spain. The patent owner (Eli Lilly & Company) sent a warning letter to the Defendant, and the latter undertook not to launch the product for which it had just obtained an MA without giving the patentee 30 days' prior notice. The patentee requested a longer notice period but the Defendant rejected the request on the following grounds:

"As early as December 2015 we gave a commitment to provide your client with 30 days' notice of intended launch in markets where the '508 patent is in force – including in Spain. Consequently, we will confirm our launch plans according to that commitment when such plans are finalized in Spain. 30 days' notice is more than adequate and you have not identified any valid reason that additional notice would be necessary. As you perfectly know the patent courts of Barcelona resolve an ex parte PI application in about 14 days, thus a 30 day notice is fully respectful of your client's rights."

Two years later, the Defendant sent a new letter to the patentee extending the undertaking accepted in the 2016 correspondence to a new product (pemetrexed diarginine) for which it had obtained an MA.

Without further ado, on 2 August 2019, when commercial courts are closed in Spain for the summer holidays, the Defendant sent a letter to the patentee pretending to be complying with the "30-day prior notice", announcing that it would launch its pemetrexed diarginine generic in the market on 2 September 2019. This low move obliged the patentee to immediately apply for a preliminary injunction, despite the fact that, as mentioned, commercial courts – the only courts with competence to deal with patent cases – are closed in August. The first working day after the summer recess, on 2 September 2019, Barcelona Commercial Court no. 4 ordered an *ex parte* preliminary injunction preventing the Defendant from launching its product. Not surprisingly, the decision mentioned twice that the Defendant had acted against the principle of good faith by giving the 30-day prior notice at a time (August) when the goal for which it had been agreed (i.e. to allow the patentee sufficient time to seek court protection of its rights) could simply not be achieved. On

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the merits of the case, the Court considered that the judgment of 12 July 2017 from the UK Supreme Court – which, as readers will know, decided with effects in England, France, Italy and Spain, in response to a declaratory non-infringement action filed by Actavis, that the scope of protection of the patent is not limited to the salt mentioned in the claim (pemetrexed disodium) – was of relevance to deciding the matter. This did not come as a surprise, either, as it is an undisputed fact that the English Courts had jurisdiction to decide that case by applying English, French, Italian and Spanish law. In fact, the parties in that case filed no less than four legal opinions from two leading professors each explaining the Spanish case law on the "doctrine of equivalents". For the reader's benefit, it should be clarified that on 10 May 2011 the Spanish Supreme Court, in a landmark *en banc* decision, confirmed a judgment from the Barcelona Court of Appeal (Section 15) that had "imported" the three-question "Catnic/Improver" test to Spain.

The Defendant filed a long writ of opposition where, among other aspects, it accused the UK Supreme Court of "judicial colonialism" for having included the following paragraph in the judgment:

"97. So far as Spanish law is concerned, it is common ground that the Spanish courts have followed the United Kingdom approach, which leads to the difficult question whether one should assume that they would follow this decision in modifying the Improver questions and in particular the second question. I incline to the view that judicial comity would tend to suggest that the Spanish courts would follow this court in modifying the Improver questions, not least because this appears to render the UK courts and therefore the Spanish courts more consistent with the German and Dutch courts, and no more inconsistent with the French and Italian courts."

Certainly it will be up to the Spanish Supreme Court to decide whether they stick to the old test or whether, like the Court from which they took the old test, they transition to the new test. In the meantime, what is clear is that the judgment of 12 July 2017, far from being an act of "judicial colonialism", is an act of judicial generosity. As transpires from reading par. 32 *et seq.* of the judgment, the Court was not happy with the poor justice resulting from applying different tests of equivalence in different countries, the undesirable consequences of which are best exemplified by the sadly famous Epilady® case. As explained in the legal grounds leading to par. 97, the modification of the old test in this case was a response to this unsatisfactory state of affairs and, in particular, a gesture from the Court to help harmonize the doctrine of equivalents in Europe.

In any event, in its decision of 9 June 2020, Barcelona Commercial Court no. 4 rejected the Defendant's opposition after noting that the diarginine salt was an equivalent variant applying both the old test and the new test. Interestingly, a few weeks before the opposition hearing the European Patent Office revoked, for obviousness, a patent owned by the Defendant's supplier that protected the pemetrexed diarginine salt.

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