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More on Pemetrexed

Brian Cordery (Bristows) · Friday, November 30th, 2012

Miquel Montana's preliminary comments on the decision of the English High Court in **Actavis v Eli Lilly** [27th November 2012] provide interesting food for thought.

Since some readers may not be familiar with the facts of the case and the relevant procedural rules in the UK, I will attempt to provide an overview before providing a few comments from a domestic perspective.

Summary of the Facts and Arguments

The decision concerned pemetrexed, the active ingredient in Eli Lilly's oncology medicine Almita®. Pemetrexed is protected by a compound patent and corresponding SPC until December 2015. Eli Lilly and Company ("Lilly US") holds an additional patent (EP 1 313 508 [the "'508 Patent'"]) which, in summary, protects the use of pemetrexed disodium in the treatment of cancer. The '508 Patent does not expire until 2021 and designates many EPC countries including the "big five" (Germany, France, Italy, Spain and the UK).

In late July 2012 Actavis issued proceedings in the English High Court for declarations that its proposed launch of pemetrexed dipotassium in the UK, France, Germany, Italy and Spain would not infringe the UK and corresponding national designations of the '508 Patent. Actavis undertook not to challenge validity in these proceedings, provided the court accepted jurisdiction. Ultimately, the questions before the Court were: (i) had Lilly US had consented to accept service in respect of the claim (including the requests in respect of the non-UK patents)? (ii) if not, had service been effected under Part 6.9(2) of the Civil Procedure Rules or "CPR" which govern the conduct of civil litigation in the English Courts; and (iii) if service was effected only pursuant to (ii), should the proceedings be stayed under the doctrine of *forum non conveniens*?

As regards (i) after considering the pre-action correspondence, Arnold J. held that Lilly US had consented to service by a letter from Lilly US's English solicitors.

The original letter, sent on 12 July 2012, from Actavis' English solicitors to Lilly US's address for service in respect of the UK patent stated as follows

*"We consider that the answer to the proposed acts [keeping selling etc dipotassium pemetrexed] should be the same across Europe in relation to the acts specified in the national provisions equivalent to section 60 of the [UK] Patents Act. Accordingly, we assume that if you are prepared to provide the declarations sought in accordance with section 71 of the Patents Act that **you will***

also be willing to provide such an acknowledgement that such acts in each and all of the jurisdictions where the Patent is in force or where the national patents specified above are registered would not infringe such patents. We should be grateful if you would also provide us with such a written acknowledgement. (emphasis added)

Lilly's solicitors responded in late July to a request from their opposite numbers that they "*were instructed to accept service [of proceedings] on behalf of their client*". This was held to amount to accepting service of the proceedings in respect of the UK and non-UK designations of the '508 Patent.

In response to an argument that consent was given only in respect of the part of the proceedings that related to the UK designation, the Court held (in a statement that might surprise a few patent practitioners):

"Counsel for Lilly argued that the correspondence had to be read against the background that claims for declarations of non-infringement of foreign designations of patents were almost unprecedented. While I accept that that is so, it seems to me that the importance of that factor is considerably tempered by the impact of the Supreme Court's decision in Lucasfilm on 27 July 2011. As any experienced intellectual property solicitor, such as those representing Lilly, would have known, that decision made it much easier for parties to argue that the claims concerning infringement and non-infringement of foreign patents were justiciable in this Court. Thus it was only a matter of time before a case such as this one presented itself."

As regards (ii) Arnold J held that even if there was no consent to service, service had been validly effected under CPR 6.9(2) because Lilly US's European Patent Operations Department constituted a place of business in the UK. This assessment was made using the leading authority of **Adams v Cape** [1990] and turned mostly on the delegation of authority to Lilly US' European Patent Operations Department based in the UK.

The Court then assessed whether the proceedings should be stayed under the doctrine of *forum non conveniens*, which rule only came into play if service was effected under (ii) above and not consented to under (i). The Judge considered the English Supreme Court's decision in **Lucasfilm v Ainsworth** [2012] that there is no subject matter limitation on jurisdiction and claims for infringement of foreign copyright were justiciable. He held that if patents were no different to copyright for the purposes of justiciability (and Lilly did not argue otherwise), there was no reason why they should be different for the purposes of *forum non conveniens* when validity was not in issue. The Court then considered whether justice demanded that the claims should be stayed in favour of a more appropriate forum (i.e. the national Courts of the non-UK designations included in the proceedings). Overall, the Judge preferred Actavis' reasons why the claims should be determined in one court, including the cost savings (only one team of lawyers on each side using one set of witnesses) and reduced risk of inconsistent decisions, over Lilly's argument based on difficulties of a court applying foreign law. Arnold J. concluded that Lilly had not shown that the courts of France, Germany, Italy and Spain were clearly or distinctly more appropriate than the English court.

Comments

The author has heard informally that this decision will be appealed. Given that this is an uncertain and difficult area, it would perhaps be surprising if Lilly did not appeal. The issues are finely

balanced and the author would not be surprised if the Court of Appeal disagreed with the approach taken by the trial judge not least because the words of Aldous J. in **Plastus Kreativ v 3M** [1995] – basically that patent issues are best decided by the courts of the country in which the patent is in force – somehow feel right to many English patent lawyers at least until the UK formally adopts a pan-European regime such as the Unitary European Patent and Unified Patent Court. But for now the decision is likely to pave the way for more pan-European declarations of non-infringement, when validity is not in issue. It may even be used to circumvent restrictive national procedural rules such as those Miquel Montana has highlighted in Spain. All patent practitioners must be alerted to the increased importance of pre-action correspondence and the dangers of inadvertently consenting to service of proceedings. All non-European patent holders should consider whether it could be argued that they have a place of business in the UK even if it is just a branch office or as in this case, a European Patent Operations Department. As a last resort, a patent holder could consider assigning individual patents to its local operating companies which would plainly not have a place of business in the UK. However this may give rise to complex tax issues for many patent holders which often prefer patents to be held centrally.

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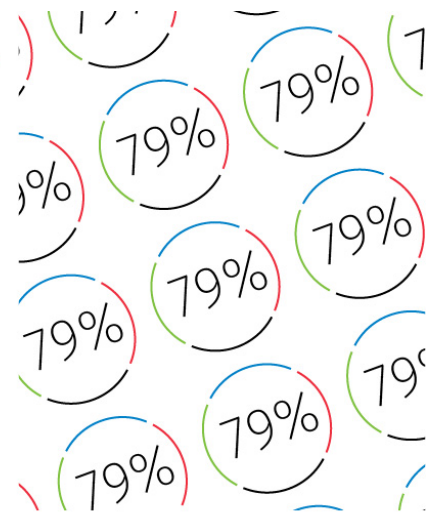
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