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# Pain and Plausibility – the UK Lyrica appeal

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Media attention at the English High Court today may have been focussed on the Article 50 challenge but for many patent lawyers operating in the life sciences sector, of equal or greater importance was the handing down of the long-awaited judgment in the Lyrica appeal.

To recap briefly, Pfizer was the owner of a patent with Swiss-type claims for the use of pregabalin to treat pain. Pregabalin, sold by Pfizer under the brand name Lyrica®, is indicated for 3 conditions – epilepsy, general anxiety disorder and pain. It was not contested that generic manufacturers (which had carved out the pain indications from their label) were entitled to sell their medicines for the first two conditions.

The decision covers three principal areas: (i) invalidity by insufficiency; (ii) post-trial amendments to patents and (iii) construction and infringement of Swiss-type claims. Each will be considered in turn:

**(i) Insufficiency**

In his first instance judgment dated 10 September 2015, Arnold J held inter alia that claim 3 of the patent in suit, which related to the use of pregabalin in the treatment of neuropathic pain, was invalid for lack of sufficiency. The data in the patent, which related to animal models of inflammatory pain, rendered it plausible that pregabalin would be effective in treating some, but not all, types of neuropathic pain (peripheral neuropathic pain but not central neuropathic pain). Both parties appealed the Judge's findings.

The Court of Appeal reaffirmed the oft repeated assertion that plausibility is a "*low, threshold test*" and that "*it is not designed to prohibit patents for good faith predictions which have some, albeit manifestly incomplete, basis*." Furthermore, the Court emphasised that the test for plausibility is not aligned with the test for whether an invention would be obvious to try i.e. for a claim to be plausible, the skilled person does not need to have a reasonable expectation of success.

The Court upheld Arnold J's rejection of Pfizer's contention that the skilled reader would assume that the patentee intended to exclude "central neuropathic pain" from the definition of "neuropathic pain". The Court noted that in some cases, where there may be two possible meanings for a term, it might be legitimate to adopt the narrower meaning if there were CGK reasons for saying that the wider meaning led to a claim extending to implausible embodiments. However, this was not such a case. Furthermore, based on this construction, the Court upheld Arnold J's view that the claim was implausible substantially on its breadth. The Court accepted that there may be cases where an

insufficiency attack focuses on a contrived or artificial part of the claim, and where, as a consequence, the attack does not undermine the validity of the claim as a matter of substance. However, once again, this was not such a case.

Finally, the Court rejected Pfizer's contention that the claim was plausible because pregabalin was shown to be anti-hyperalgesic. The Court upheld Arnold J's rejection of this as a "unifying characteristic". Furthermore, it was not fully developed as part of Pfizer's case and the evidence as a whole did not support it.

**(ii) Post-trial amendment**

Arnold J had found that had claim 3 been restricted specifically to peripheral neuropathic pain (i.e. excluding central neuropathic pain), it would have been sufficient. After the decision had been handed down, Pfizer made an application to the Court to amend its patent to include a claim to peripheral neuropathic pain. This application to amend was dismissed by Arnold J in a decision dated 25 November 2015 as being an abuse of process. Pfizer appealed this finding arguing that the attack on the sufficiency for central neuropathic pain was not articulated by the challengers in sufficient time for Pfizer to be able to deal with it at the trial.

Following a long line of authority including **Nikken v Pioneer** [2005] and **Nokia v IPCom** [2011], Floyd LJ held that it was necessary to distinguish between pre-trial applications to amend and post-trial deletions on the one hand, and post-trial validating amendments by re-writing the claims on the other. Floyd LJ noted that the Court should be cautious in allowing the latter type of amendment as it would be likely to create new issues which were unlikely to have been decided at trial. After a lengthy discussion, it was held that Pfizer should have indicated to the trial judge, no later than the start of the trial, that in the event of a finding of insufficiency of claim 3, it would seek to amend. Raising the issue at this stage, would have enabled the Court to case manage the situation.

**(iii) Infringement**

Readers will recall that Floyd LJ set out his views on the interpretation of Swiss-form claims and on indirect infringement in the appeal of Pfizer's preliminary injunction applications, precisely so that the parties would know the position at the main infringement trial (of which the present judgment is the appeal). However, recognising Arnold J's reluctance to follow this dicta, and accepting that the issue "*remains of great difficulty*", Floyd LJ did provide some additional commentary (albeit obiter, having found the patent to be invalid).

Unsurprisingly, Floyd LJ referred back to his earlier statements, confirming that when considering intention, an objective approach is necessary, and that "*from an objective standpoint, one would normally regard a person to intend what he knows or can reasonably foresee as the consequences of his actions*." He also confirmed that "*the intention will be negatived where the manufacturer has taken all reasonable steps within his power to prevent the consequences occurring*" at which point the foreseen consequences (of use for the patented indication) become unintended. There is surely, great scope to argue what "*all reasonable steps*" involves, but it is very clear that generics companies will have to take substantive steps beyond carving-out the patented indication and half-hearted attempts to prevent cross-label use will not be sufficient.

On the test for indirect infringement, Floyd LJ reiterated that what is required is that means are provided which are for putting the invention into effect, but that there is no requirement for a

"*downstream act of manufacture*". Floyd LJ agreed with Pfizer that the process of the invention would be put into effect by the pharmacist ascribing the patented purpose to generic pregabalin (in this case by the labelling step performed by the pharmacist). He went on to observe that, contrary to previous statements from Arnold J, he did not understand why other acts of the pharmacist in preparing the composition for delivery to the patient could not also be regarded as relevant acts of preparation, if done with the necessary intention. Notwithstanding that this is all *obiter*, as other cases come through the UK Courts in relation to different medicines and different prescribing/dispensing practices, it will be interesting to see how broadly the Courts are prepared to interpret these statements.

**Commentary**

Floyd LJ's analysis of the issue of plausibility is interesting and patentees will be pleased to see the Court of Appeal has reiterated that plausibility is a relatively low, threshold test.

The failed post-trial amendment application serves as a stark reminder to patentees that even in the intensity of trial preparations, it is necessary to step back and consider whether it would be appropriate to apply to amend the patent in suit to include certain fallback positions just in case. Attempts to amend after the trial will rarely be successful.

This judgment also underscores that the act of carving out the patented indication from the label is a necessary, but not sufficient, act for a generic manufacturer to absolve itself from potential infringement of an indication patent.

Finally, in the authors' view, the approach taken by the Court of Appeal to the issue of indirect infringement is legally sound and aligned with certain other Courts around Europe. In this regard, the issue of indirect infringement is due to be considered by the Supreme Court in the pemetrexed case next spring and it will be interesting to see how the UK's highest Court deals with this potentially complicated area of the law.

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