Carving out the principles: a comparative review of the Australia and UK Lyrica cases

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On 21 October 2016, the Federal Court of Australia handed down its judgment in the case of *Apotex Pty Ltd v Warner-Lambert Company LLC (No 2)* [2016] FCA 1238 (**FCA Judgment**). Justice John Nicholas found in favour of Warner-Lambert, both upholding the validity of its patent claims and granting final injunctions restraining infringement by Apotex.
The case also provides a useful comparator for the England and Wales Court of Appeal's judgment on 13 October 2016 in *Warner-Lambert Company LLC v Generics (UK) Ltd (t/a Mylan) & Ors* [2016] EWCA Civ 1006 (**EWCA Judgment**) (covered by Brian Cordery of Bristows in 'Pain and Plausibility – the Lyrica Appeal'), particularly with respect to how Australian and English law determine sufficiency and infringement of Swiss-style claims. The EWCA found the comparable UK claims to be invalid for insufficiency.

Preliminary Relief

The Australian case concerned Warner-Lambert's 714980 patent for methods of use for the drug pregabalin for the treatment of pain (**Pain Patent)** and in the manufacture of a medicament for such treatment. In particular, claims 16, 17-30 and 32 of the Pain Patent were Swiss-style claims, with the balance being method claims.

In 2014 Warner-Lambert had sought a preliminary injunction restraining Apotex from supplying its own pregabalin products, including for uses other than the treatment of pain (such as for treatment of seizures), because of the high likelihood that the generic products would be supplied for an infringing use. Initially the Federal Court granted only a narrow injunction, limited to use of pregabalin for the treatment of neuropathic pain, which reflected the product's label. However, on appeal the preliminary injunction was broadened to enjoin the supply of pregabalin for non-pain indications as well, despite Apotex having belatedly registered a "skinny" label, excluding treatment for neuropathic pain. The appeal Court expressly acknowledged the possibility of off-label use for these indications, even though the market for these indications was accepted to be small to non-existent.

A similar appeal in the UK from the trial judge's refusal to grant a preliminary injunction was unsuccessful.

At the final trial in Australia, the generic companies cross-claimed that the Pain Patent was invalid on the grounds of false suggestion, lack of utility and insufficiency. Justice Nicholas easily rejected the false suggestion argument on the evidence, but gave greater attention to utility and sufficiency.

Utility

The generics contended that pregabalin was not effective in the treatment of pain that did not involve neuropathic or central sensitisation. It was therefore said to lack utility under section 18(1)(c) of the Patents Act. A similar argument was made before the UK courts.

Justice Nicholas outlined that section 18(1)(c) did not require an invention to be "*commercially desirable or preferable to other products or processes in the field*" for it to be useful. A claim may have utility even if a promised advantage cannot be achieved in all cases, or is achieved with less success in some areas.

In this case, Pfizer's expert evidence supported the view that all pain conditions "*involve some element of central sensitisation*", even if it is so slight as to be of no clinical relevance in some instances. This evidence was similar to that of Professor Woolf tendered by Pfizer in the UK litigation, but did not involve any finely drawn distinctions between the role of central sensitisation in central and peripheral neuropathic pain. In fact, Nicholas J noted that:

- claim 1 was not limited to a method of treating neuropathic pain, nor to pain associated with central sensitisation;
- the expert evidence was that the extent of the therapeutic effect achieved using pregabalin in cases where central sensitisation played only a minor role was likely to be slight, but it was not non-existent.
- the Pain Patent specified a dosage range of up to 300mg/kg body weight, and that the range may be varied even further upward; and
- the Lyrica product information contemplated doses of up to 600mg/kg.

The generic company expert witnesses did not contradict this evidence, but emphasised that pregabalin was not an effective treatment, and would not be prescribed by a doctor, for some types of pain such as acute pain associated with disc disease or acute gout pain.

However, the Judge held that this evidence did not establish that Lyrica would not give at least some measure of pain relief for such patients at the doses contemplated by the Pain Patent and/or the product information, however minor. As the Pain Patent made no representation as to the "*degree*" of pain relief achieved by the drug, the giving of "*some measure*" of relief to "*a substantial number of patients in need of treatment for pain"*, the claim will not lack utility.

Sufficiency

Section 40(2)(a) of the Patents Act requires a complete specification to "*fully describe*" the invention. The case law requires the patent to enable the skilled addressee to "*perform the claimed invention in relation to humans without new inventions or additions or prolonged study of matters presenting initial difficulty*". It should be remembered that the safety and efficacy testing data in the Pain Patent was derived from animal trials only, although the claims were directed to treatment of pain in mammals.

The generics contended that the Pain Patent imposed an "*undue burden*" on the skilled addressee, reflecting the "classical insufficiency" test adopted by successive UK cases. Pregabalin was said to be a new chemical entity that had not been tested on humans – therefore, further research was required to understand the safety and toxicity profile of the drug, and its efficacy in humans. The need to undertake further research would amount to an "*undue burden*" being placed on the skilled addressee.

The Court rejected this analysis, indicating that the Pain Patent was clearly directed to the treatment of pain in mammals, in particular humans, and that the description in the patent will be sufficient if the steps required to work the invention are readily apparent to the skilled addressee, and they are standard or routine steps within the skilled addressee's competence.

The judge held that the "*undue burden*" concept in English law (particularly as outlined by Arnold J in *Eli Lilly v Janssen* in 2014) was not particularly helpful under Australian law. The question was not whether the patentee could have supplied the skilled addressee with more information, but whether the skilled addressee had enough information to enable the working of the invention from a combination of the common general knowledge and the patent. The judge said that:

> *"the description of the invention will not be insufficient merely because the skilled addressee is expected to apply considerable skill, effort and resources to make it work. If the steps required ... are readily apparent to the notional skilled addressee, and they are standard or routine steps within the competence of the skilled addressee, the test for sufficiency will be satisfied".*

This statement makes it clear that the Australian Court is content for some burden to be placed on the skilled addressee to work the invention. That burden may even be "considerable" and may involve testing for oral bioavailability, toxicity and effectiveness, so long as those steps are essentially routine for those skilled in the area. However, the burden would be too much if the skilled addressee was required to undertake "*new inventions or additions or prolonged study of matters presenting initial difficulty*".

In this case, there was no evidence to suggest that the animal studies and pre-clinical work undertaken by Pfizer would have presented the skilled addressee with any problems that would be either difficult to resolve or beyond the competence of a notional team engaged in routine testing.

In contrast, the EWCA found the same claim to fail for insufficiency because there was no basis for saying that it was plausible that pregabalin would be effective for all types of pain. This conclusion was clearly based on the evidence presented to the Court. As noted above, the evidence in the Australian case was quite different.

In practical terms, despite eschewing somewhat the notion of "undue burden", the Australian Court did engage in a review of the "burden" placed on the skilled addressee, but simply analysed it in a slightly different manner, focusing on the routine nature of the tasks needed to work the invention.

It could be argued that the difference in outcomes between Australia and the UK was primarily an evidentiary one – the expert evidence before the EWCA indicated that pregabalin could *not* be used for the treatment of every pain context and, therefore, the claim was implausible due to its breadth – but Nicholas J effectively found that there was adequate support in the patent for efficacy for all types of pain.

Swiss Claims – Direct Infringement

In the Australian proceedings, the Court affirmed Justice Yates' approach in *Otsuka Pharmaceutical Co Ltd v Generic Health Pty Ltd (No 4)* (2015) 113 IPR 191, namely that the question of infringement of Swiss type claims was viewed through the prism of paragraph (b) of the definition of "exploit" in Schedule 1 of the Patents Act, which extends infringement to the use of the claimed method via a product resulting from such use.

Apotex argued that paragraph (b) of the definition of "exploit" imported a territorial limitation, in that it only applied to exploitation of the invention within the "patent area", i.e. Australia, and that the importation or supply of a product in Australia made by the claimed method outside Australia was not an infringement.

Justice Nicholas summarily dismissed the argument. His Honour held that the definition of "exploit" made no reference to the patent area, and that the relevant act of infringement was not the use of the method outside of the patent area but, as specified in the definition, the exploitation (by importation or supply) in Australia of a product resulting from using the patented method.

His Honour therefore concluded that Apotex would be exploiting, and directly infringing, the patented method if it manufactured its pregabalin product overseas, but then imported and sold it in Australia. This conclusion involved no analysis of the manufacturer's or importer's intention, but was simply a question of fact to be proven.

However, in the UK, the Lyrica case shows that a manufacturer's intention was a relevant consideration for direct infringement of a Swiss claim. Floyd LJ's comments at paras 205-208 EWCA judgment as to what a generic manufacturer may reasonably foresee as a consequence of his actions (presumably including likely use of a product for an infringing indication, whether off-label, cross-label or otherwise) are a variation on a theme found in Australia's indirect infringement provision – s 117(2)(b) – which requires the manufacturer to have "reason to believe" that the product will be put to an infringing use, which implicitly involves some exploration of intention. The "reason to believe" assessment is objectively made. Floyd LJ's view that a manufacturer could "negative" the intention if it had taken "*all reasonable steps within his power*" to prevent the consequences from occurring, also requires an objective analysis of the manufacturer's state of mind.

Conclusion

The different outcomes in the Lyrica litigations in the UK and Australia appear to have resulted more from matters of expert evidence than major variations in application of legal principle, but it is also possible that

these cases are a further example of the fact that, as observed by the High Court of Australia in the omeprazole litigation in 2002, the UK Courts now consistently require something more than the “scintilla” of sufficiency or level of invention necessary for a patent grant in Australia, or indeed in the pre-1970 UK cases.