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A burden to bear – a brief comparison of Lyrica and the test for sufficiency in Australia and UK

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Two recent decisions in the UK and Australia in the long-running pregabalin litigations demonstrate the different approaches in these jurisdictions to determine if a patent specification has sufficiently disclosed an invention. Readers will recall that the judgments concerned Warner-Lambert's Swiss-style claims for the use of the compound pregabalin (marketed as Lyrica) in the treatment of pain.

On 14 November 2018, the UK Supreme Court handed down its judgment in *Warner-Lambert Company LLC (Appellant) v Generics (UK) Ltd t/a Mylan and another (Respondents)* [2018] UKSC 56. The Court found that Warner's Lambert's claim for a second medical use failed for insufficiency as the relevant patent claims did not meet the threshold for plausibility for the treatment of neuropathic pain of any kind.

However, on 23 February 2018, the Full Federal Court of Australia (**Full Court**) in *Warner-Lambert Company LLC v Apotex Pty Limited (No 2)* [2018] FCAFC 26 had found that the equivalent claim sufficiently disclosed the invention.

Though the evidence before the courts was quite different, the Full Court and the UK Supreme Court each noted that the divergent evolution of legal principle had contributed to different outcomes. In its reasons, the UK Supreme Court summarised the possible approaches as:

1. ***"Biogen insufficiency"*** (of which "plausibility" is one factor) : where the claim is said to be too broad because it exceeds the disclosed contribution to the art; and
2. ***"Classical insufficiency"*** : derived from pre-1977 UK case law, where the skilled person is unable to perform the invention from the information disclosed in the specification.

The "plausibility" requirement reflects UK case law's harmonisation with the practice and decisions of European Patent Office (**EPO**). On the other hand, the Full Court clarified that "classical insufficiency" is the relevant test in Australia.

"Undue burden" inapplicable in Australia

In Australia, sufficiency under section 40(2)(a) of the *Patents Act 1990* requires that the notional skilled addressee can "*perform the claimed invention in relation to humans without new inventions or additions or prolonged study of matters presenting initial difficulty*" (the **Kimberly-Clark test**). In the pergabalin case the generics contested the application of this test, submitting that:

- the Kimberly-Clark test was no more than a "*commonly applied test for sufficiency*"; and
- the broader test of "undue burden" was more appropriate to determine sufficiency. This was because an invention could not be "fully described" for the purposes of section 40(2)(a) if an "undue burden" was placed on the person skilled in the art who wishes to use the claimed method / make the claimed medicament. Such a consideration was particularly relevant for Swiss-form claims involving second medical uses. It was noted that "undue burden" is applicable in the EPO's approach to establishing the plausibility of a claim in a patent specification.

The Full Court rejected the generics' submissions. It considered the origin and application of the "undue burden" test in depth and noted that "undue burden" was introduced into UK case law so that the UK Patents Act was applied "*consistently and harmoniously*" with the European Patent Convention (**EPC**). These considerations were foreign to Australian patent law. The Court stated unequivocally that:

> "*So far as we are aware, the expression "undue burden" has not entered the lexicon of Australian patent law with respect to s 40(2)(a) of the Act, which relevantly requires that the complete specification of a patent application describe the invention fully. Caution must be exercised when considering what is intended to be conveyed by "undue burden" in this context.*"

In the Court's view, applying "undue burden" in an Australian context is:

> "*really an invitation to expand the scope of operation of s 40(2)(a) in a way not envisaged by the High Court in Kimberly-Clark, by reference to a little-explained and somewhat indeterminate standard. It is also an invitation that runs counter to the High Court's caution against an uncritical adoption of post-1977 United Kingdom cases on provisions that are, at best, only broadly similar to provisions in our own Act … This is an invitation we should decline*"

Months later in the UK Supreme Court's reasons, Lord Sumption agreed with the Full Court's view on the jurisdictional differences. His Lordship noted that Australian courts analysed the question solely in terms of classical insufficiency and that EPO practice and post-1977 UK case law were irrelevant to its statutory context. The UK Supreme Court however was required to take a different course.

The "plausibility" requirement in UK law

As noted in our review of the lower court Lyrica judgments, UK case law requires a higher threshold than is necessary for a patent grant in Australia. The majority's reasons further ingrained this point of view. The majority found that "plausibility" was not a low threshold (as indicated in lower court decisions) but required the specification to do more:

> "*the specification must disclose some reason for supposing that the implied assertion of efficacy in the claim is true. Plausibility is not a distinct condition of validity with a life of its own, but a standard against which that must be demonstrated*"

The majority held that the test was "*relatively undemanding*" but could not be reduced to "*little more than a test of good faith.*" Plausibility required that the patent should disclose "*not just what the invention is and how to replicate it, but some reason for expecting that it will work*".

Having reviewed the evidence before the lower courts, the majority held that the patent application "*did not contribute any knowledge of the art capable of justifying a claim to a monopoly of the manufacture of pregabalin for the treatment of neuropathic pain of any kind*".

Disorder in harmony

The UK Supreme Court noted that the UK would be the only EPC jurisdiction (up to that time) to find the relevant claims to be insufficient. Lord Sumption considered that it would be "*unfortunate*" if courts in other EPC jurisdictions came to different conclusions, but noted that much depended on "*how far the factual and technical evidence before the foreign court was the same*".

The harmonisation of sufficiency law would certainly be of assistance to the commercial interests lying behind second medical use patents. However, the approach of the UK Courts, as evidenced by the decision of the UK Supreme Court, continues to be skewed towards finding reasons to invalidate patents, rather than to uphold them.

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