

Swiss Form Claims and Skinny Labelling - the Lyrica Appeal

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On 28 May 2015, the English Court of Appeal issued a ruling in the on-going Lyrica saga which, although almost certainly not representing the last word on the topic, took a markedly different approach to the correct construction of Swiss form claims to the first instance judge, Arnold J. One thing there does appear to be agreement on at least is that this is an important, yet difficult, subject matter.

The Lyrica litigation is active in several European countries (as well as further afield, e.g. Australia) and so the background will be familiar to many readers. In short, towards the end of January this year, Arnold J refused to grant interim relief against Actavis in respect of Warner Lambert's patent with Swiss form claims for the use of pregabalin to treat pain. The Judge held that: "*the word 'for' in Swiss form claims imports a requirement of subjective intention on the part of the manufacturer that the medicament or pharmaceutical composition will be used for treating the specified condition*" (emphasis added). As the Judge considered that there was no evidence before the Court that Actavis possessed such a subjective intention, he found that there was no serious issue to be tried in respect of infringement and thus Warner Lambert failed to satisfy the first limb of the *American Cyanamid* test that continues to apply in considering whether to grant a Preliminary Injunction. Arnold J also considered the second limb of the *American Cyanamid* test - the balance of justice - and found that this also favoured Actavis. In subsequent decisions in early February, Arnold J allowed Warner Lambert's claim of direct infringement to proceed to trial but struck out the claim to indirect infringement, on the basis that he considered Warner Lambert's claim relied on construing the Swiss-form claim as a product claim, or analogous thereto, whereas the Judge was in no doubt that it was established UK law that Swiss form claims were process claims.

Warner Lambert appealed both decisions and the case came before the Court of Appeal in late April. In the appeal, Warner-Lambert ran different arguments in relation to indirect infringement which were not predicated on the claims being product claims or analogous to product claims. The Court of Appeal, (Floyd LJ giving the leading judgment) issued a unanimous decision on 28 May.

In relation to the application for interim relief, the end result was that the Court of Appeal upheld Arnold J's decision not to order the measures sought by Warner Lambert on the ground that Arnold J had properly evaluated the evidence before him and reached a sensible conclusion on the balance of justice. However, perhaps more significantly, the Court reached an alternative view on the correct approach to be taken to the construction of Swiss form claims that will have a significant impact on the assessment of the infringement of such claims in the future. Whether or not one ultimately agrees with Floyd LJ, there is no doubt that the decision is the well-reasoned product of a fine legal brain.

In reaching its conclusion and, in contrast to Arnold J, the Court of Appeal held that the term "for" in such claims does not require subjective intent on the part of the manufacturer. Instead the key is what the manufacturer knows (including constructive knowledge) or could reasonably foresee about the ultimate intentional end use of the product for the patented indication. So, in the appeal court's view, infringement will occur if the manufacturer knows or can reasonably foresee the ultimate intentional use for pain. The manufacturer does not necessarily need to have that specific intention or desire itself.

The Court of Appeal's construction is based on the skilled person's understanding of the invention; the skilled addressee would understand that the technical features of such a claim go beyond the making of pregabalin and extend to its ultimate end use - i.e. the step in the process from which novelty is derived. The subject matter of the claim is "*making pregabalin for patients to whom it will be intentionally administered for treating pain*".

The Court of Appeal also reversed Arnold J's decision to strike out the indirect infringement claim meaning that it will progress to trial in June 2015 alongside the claim for direct infringement. The Court of Appeal was principally swayed by three factors. First, the fact that, while jurisprudence in EU member states is not settled, the Courts in both Germany (*Warner Lambert v Aliud*) and the Netherlands (*Novartis v Sun*) have granted relief for indirect infringement. Secondly, the Court held that on the basis of the above construction, there may be a case of threatened or actual infringement of a process claim (s60(1)(b)), so it must be that downstream acts of dealing in the product of the process may infringe (s60(1)(c)). Finally, the Court suggested that it is arguable that "putting the invention into effect" in s60(2) may occur when one person manufactures and another uses the product for the patented indication.

Also of note is the Court of Appeal's dismissal of the Secretary of State's application to intervene. The Secretary of State argued that in order to protect doctors' freedom to prescribe, the method of treatment exception must affect the construction such that doctors practising a method cannot be infringing. As such, it argued that any knowledge requirement must be confined to the manufacturing stage. The Court of Appeal noted that the identity of the infringer cannot affect the construction of the claim (in particular, its determination of the technical subject matter), nor would the proposed construction prevent downstream users from infringing, as they would be dealing in products obtained by an infringing process.

The case will now proceed to trial at the end of June and the beginning of July. It will be interesting to see what the trial judge makes of the Court of Appeal decision, particularly given Floyd LJ's observation that "*the judge found that in these circumstances, it was foreseeable that a generic version of Lyrica with a skinny label will be dispensed for patients who have in fact been prescribed the drug for pain*." Either way, an appeal is almost certainly inevitable and it is not hard to imagine these issues eventually being considered by the Supreme Court such is their complexity and importance.

Meanwhile, earlier in the week, the Court of Appeal's website was indicating that judgment would also be handed down on 28 May in the Actavis v Eli Lilly case concerning pemetrexed which also relates in part to the construction of Swiss form claims as well as several other important issues such as cross-border relief, claim construction and use of the file wrapper to interpret the claims. Disappointingly, for reasons unknown to the authors, this decision was not handed down as indicated. We will continue to monitor the situation and report on this as soon as we can.

by Claire Phipps-Jones and Brian Cordery