# Kluwer Patent Blog

## Swiss-Form Claims, Skinny Labelling and the duty of the National Health Service – the Lyrica case continues

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At the end of January, we reported the **Warner-Lambert v Actavis** decision of 21 January 2015, in which Arnold J refused to grant Warner-Lambert interim relief in relation to an apprehension of patent infringement by Actavis of Warner-Lambert's patent comprising Swiss-form claims directed to the use of pregabalin in the preparation of a medicament for the treatment of pain. The apprehended patent infringement pertained to Actavis' generic pregabalin medicine. Actavis had carved-out pain indications from the label for its medicine but it was nevertheless foreseeable that some of these medicines would be dispensed and used for pain in the UK.

The judge refused to grant an interim injunction as he considered that there was no serious issue to be tried on the issue of patent infringement and that the balance of convenience favoured Actavis in any event. That decision has now been appealed and the appeal will be heard in late April.

The challenge encountered by Warner-Lambert ultimately stems from the way that medicines are prescribed and dispensed in the UK. At the present time, physicians are encouraged (though not obliged – see below) to write prescriptions using the INN or generic name for the drug (e.g. "pregabalin" not "Lyrica") and the indication is also generally not noted on the prescription. This means that the pharmacist dispensing the medicine in fulfilment of the prescription will usually not know the intended use of the drug. Moreover the UK healthcare system is geared to encourage the pharmacist from a financial perspective to dispense the cheapest medicine in stock.

In his judgment of 21 January, Arnold J noted the above issue and suggested that the "best solution" to the problem encountered by Warner-Lambert was for the NHS to issue guidance recommending that doctors should prescribe pregabalin by brand (i.e. "Lyrica") for the treatment of pain and to prescribe pregabalin generically for other indications. Because pharmacists in the UK would be legally obliged to dispense the branded medicine to fulfil prescriptions written for the brand, if doctors adhered to the guidance, this ought to ensure that the generic medicine was not dispensed for the patented indication. The Judge also encouraged software providers to amend their electronic prescription systems to prompt doctors to prescribe branded pregabalin for pain. Arnold J commented that "*I consider that there is a reasonable prospect of NHS England issuing guidance in the near future but a lower prospect of software suppliers*

*modifying their software quickly.*"

No doubt spurred on, at least in part by the observations of the Judge, Warner-Lambert wrote to NHS England on the day after the judgment was handed down to ask it to issue guidance to Clinical Commissioning Groups ("CCGs"). At first, NHS England expressed a reluctance to opine on the correct formulation of prescriptions for pregabalin, at least on a timescale that was likely to be material to the litigation at hand. However, following further correspondence in which Warner-Lambert indicated an intention to make an application to Court for the NHS to be compelled to issue the relevant guidance, NHS England subsequently changed its position and indicated it would not oppose an Order provided that certain conditions were met.

Warner-Lambert duly issued an application and the matter came before Arnold J on 26 February. The hearing was attended by representatives from several generics companies as well as Warner-Lambert and NHS England. Although the Order was for the most part uncontested, the Judge nevertheless considered whether the Court had jurisdiction to make the Order and whether the injunction was appropriate in all the circumstances.

As regards the question of jurisdiction, Warner-Lambert relied upon the decision of Arnold J in **Cartier v B Sky B** last year to suggest that the Court was empowered to make the Order sought. For its part, NHS England agreed that the situation was "obviously comparable to **Norwich Pharmacal**" – a principle which allows the Court to make an Order against an innocent third party mixed up in the wrong-doing of others. Despite noting the difficulty that, on his own view as expressed in his decision of 21 January, there was no wrong-doing as such, Arnold J observed that this was a developing area of the law and that the appellate Court might reach a different conclusion on construction and infringement. Further, he noted that there was an analogy with the decision of the Court of Appeal in **Novartis v Hospira** (where an interim injunction was granted to preserve the position notwithstanding the patent in question having been adjudged to be invalid following a first instance trial). Arnold J thus considered that there was jurisdiction to grant the Order. Warner-Lambert also relied upon **Broadmoor v Robinson** to contend that the Court had jurisdiction to enforce a public law duty in private law proceedings but Arnold J did not examine this point in detail.

Arnold J then went on to consider whether it was appropriate to grant the Order in all the circumstances. In line with the **Cartier** case, he noted that, notwithstanding that the parties were professionally represented and had negotiated the Order, the IP Enforcement Directive required the Order to be proportionate, not represent a barrier to legitimate trade and contain safeguards against abuse. The Judge considered the relevant provisions of the Charter of Fundamental Rights of the EU and concluded that: "*the issuing of guidance by NHS England is the most efficacious, dissuasive and cheapest solution to the problem which confronts Warner-Lambert*".

The court next considered the scope of the cross-undertaking that should be given. Warner-Lambert agreed to provide a cross-undertaking in damages in favour of NHS England and the Court ordered the cross-undertaking to extend to those generic companies that applied for it and their group companies. relying on the earlier

authority of **Actavis v Boehringer Ingelheim**. Arnold J.'s willingness to order such an undertaking in favour of the generic companies was based on the possibility that the patent was later held invalid, and also, even if the patent was held valid, the possibility that the guidance would have the effect of Lyrica being prescribed and dispensed at the expense of generic pregabalin for non-patented indications (referred to as "a chilling effect"). Finally, it is worth noting that the Order made by Arnold J. makes provision for additional guidance to be issued when the patent expires (or earlier in the event that the patent is revoked). The essence of the additional guidance is that practitioners should revert to their normal prescribing practices and that any software modifications should be reversed.

This decision emphasises the Court's acceptance that, under the current regulatory systems in the UK, it is difficult to effectively prevent cross-label use and as such to enforce second medical use patents. However, it remains to be seen whether the novel approach adopted by the Court will prove to be transferable to other cases. Ultimately on this occasion both originators and generics have the same goal – namely to allow free competition in the market for non-patented indications whilst respecting the legal exclusivity for the patented indication. Given the commonality of purpose, it is to be hoped that meaningful results can be achieved.

The problem over the interpretation of Swiss-form claims will gradually diminish and disappear altogether in approximately 2035, as they are superseded by "EPC 2000" claims. However, in the interim, we expect enforcement of such claims to continue to be a hot topic throughout Europe, not least until the construction of such claims is settled and the form of interim and final remedies effectively determined, or until regulatory systems are changed so that patent protection for new uses of existing drugs is properly taken into account. The legal issues may ultimately be destined for the Supreme Court both in the UK and elsewhere. The first chapters in the Lyrica story have been written but much of the story remains to be told.

By way of final comment, it is interesting to note that just over 20 years ago, the EPO's Enlarged Board of Appeal in **Eisai** bemoaned the lack of guidance from the Supreme Courts of EPO Member States on how to give effective patent protection for second medical uses so as to incentivise research into this important area whilst at the same time not colliding with the prohibition against methods of treatment of the human or animal body. Two decades on, it is surely time for such guidance to be given.

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This entry was posted on Friday, March 27th, 2015 at 5:04 pm and is filed under Second Medical Use, United Kingdom
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