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Second medical use claims – The English Court embarks on a painful odyssey

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With huge financial incentives for early launch of generic drugs after patent expiry, it is surprising that court cases on second medical use patents have been so rare in the UK (and elsewhere in Europe). This makes UK High Court proceedings over pregabalin, marketed by the Pfizer company Warner-Lambert ("WL") as "Lyrica" for epilepsy, generalised anxiety disorder ("GAD") and neuropathic pain, a case worth watching, with Actavis accused by of infringing WL's second use patent for treating pain.

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Background

Following expiry of the product patent and of data exclusivity the remaining barrier to generic products in the UK was the second medical use patent with "Swiss form" claims:

1. Use of [pregabalin] for the preparation of a pharmaceutical composition for treating pain.
3. Use according to claim 1 wherein the pain is neuropathic pain.

Swiss form claims have not been allowed by the EPO for applications filed after 11 December 2009. "Purpose limited product claims", have been introduced instead, but patents with Swiss form claims will remain in force for many years to come.

Actavis sought a so-called "skinny label" Marketing Authorisation ("MA") for use in epilepsy and GAD, so its Summary of Product Characteristics (SmPC) and Patient Information Leaflet ("PIL") would not include the indication of pain. However, omitting an indication from the SmPC and PIL does not prevent a generic product from being prescribed or dispensed for that indication.

In the UK, if a drug is prescribed by brand name, the pharmacist must dispense that brand, but prescribers are encouraged by guidance from national/local health bodies, and prescription-writing software to prescribe using the generic name. As medical practitioners rarely write on the prescription the condition for which the drug is prescribed, the pharmacist does not normally know the condition to be treated and it is not practicable for them to find this out. Data showed that a substantial proportion of pregabalin is prescribed for neuropathic pain. Clearly, in practice, doctors were going to prescribe pregabalin generically without indicating the condition and Actavis's product was inevitably going to be dispensed to some patients who were to be treated for neuropathic pain.

In pre-action correspondence WL had requested Actavis take various measures to ensure their product would not be prescribed for pain. Whilst Actavis had already taken certain measures (notably adoption of the "skinny label") and had apparently agreed to certain others, WL were not satisfied and therefore commenced infringement proceedings requesting an interim injunction to prevent Actavis from launching at all.

Construction of "Swiss form" claims and test for infringement

What if, notwithstanding the skinny label, the generic product were prescribed for neuropathic pain – would the generic supplier infringe? If so, what

steps should the generic supplier be obliged to take pending full trial?

The judge followed previous case law in assuming that the Swiss form claim is directed at the manufacturer. He then needed to consider whether Actavis's product was "for treating pain". In the context of claim 1 "for" meant "suitable and intended for". At issue were whose intention was relevant, and what is meant by "intended".

The Court disagreed with WL's submission that the relevant intention was that of the person who disposes, or offers to dispose of, the product, and concluded that the relevant intention is that of the person who carries out the process (i.e. in this case Actavis).

On the meaning of "intended", WL contended it was sufficient that Actavis intended to sell pregabalin and knew that pharmacists were likely to dispense it for treating (neuropathic) pain if positive steps were not taken to prevent this. However, Actavis successfully argued that a duty to take such positive steps can only arise where the party knows of infringement by another – which they did not, given that Swiss form claims are directed at the manufacturer. The judge concluded that the word "for" in such claims imports a requirement of subjective intention on the part of the manufacturer that the medicament will be used for treating the specified condition. As WL had not pleaded subjective intention, there was no serious question to be tried, so their application for interim relief failed.

Upon this finding, WL successfully applied for permission to amend its case to plead subjective intention, despite Actavis's application for the case to be struck out. These applications were considered in a further hearing in February 2015, amendment of WL's case being permitted whilst Actavis's request for striking out failed. Although almost all of WL's possible grounds for inferring subjective intention failed to impress the Judge, a recent case before the Dutch Courts (Novartis v Sun) persuaded him to acknowledge there was a developing area of law such that the requested amendment should be allowed. Nevertheless the Judge observed that the facts of the Dutch case were different and implied disagreement with the Dutch court's interpretation of Swiss form claims.

What measures might reasonably be expected of third parties?

In the pregabalin case, after NHS England stated that it would not alter its prescribing guidance until it was ordered to do so by a Court, the Judge made an unusual Order requiring NHS England to issue guidance in agreed form for prescribers and dispensers. This specifies that GPs should only prescribe pregabalin for the treatment of neuropathic pain under the brand name Lyrica, writing only the brand name and not the generic name pregabalin or any other generic brand; that pharmacists should ensure that, if they have been told it is for the treatment of pain only Lyrica is dispensed; and that electronic prescription systems within the power or control of the relevant bodies should be amended accordingly.

The jurisdiction of the Court to make such an Order was not challenged, and nor were its contents resisted. It appears to have been granted by the Judge for reasons of judicial expediency, and is subject to terms as to withdrawal of the guidance in the event that the patent is revoked and to cross-undertakings in damages in favour of NHS England, Actavis and others. The Court of Appeal's judgment on some of these preliminary points (currently awaited) is bound to be of great interest.

Concluding remarks

Although the decision on interim relief may imply that the Judge considers the case on infringement to be weak the issue has yet to be argued in full trial, currently scheduled for June 2015. At the time of writing, the judgment of the Court of Appeal in WL's appeal against the refusal to award an interim injunction is keenly awaited, and it seems certain that the final decision at first instance will also be scrutinised closely in an appeal.

Some parties have in the past had doubts about the enforceability of Swiss form claims. The signs for the time-being are that the Courts will enforce these claims fully, despite the practical challenges involved. That is something to be welcomed by rights holders.

Extrapolation of this case to European jurisdictions other than the UK involves difficulties. Increasing harmonisation of approach has improved the consistency of decision-making within Europe but, in this case, questions of claim construction and application of the relevant patent law are complicated by fundamental differences between healthcare systems in different EU countries, highlighted by the Dutch case of Novartis v Sun.

If you have any questions concerning this article or any related matter please feel free to contact us at ai@patentable.co.uk

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