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Swiss Form Claims and Skinny Labelling – the Lyrica Case

Brian Cordery (Bristows) · Friday, January 30th, 2015

Most readers will know that so-called Swiss form claims ("Use of drug X in the manufacture of a medicament for the treatment of disease Y") were first proposed by the Enlarged Board of Appeal of the EPO in the **EISAI** case back in December 1984 to allow new uses for known drugs to be patented. This area is of considerable importance, because, as was set out in the resolution of AIPPI on this issue passed at the Toronto congress in September 2014: "*Second medical uses may provide solutions to unmet medical needs and provide significant benefits to patients. They may require significant investment in research and development and represent socially, medically and economically valuable innovations.*" It is noteworthy that the EBA in **EISAI** were tempted to follow the jurisprudence of the German Courts which, at the time, allowed claims to "use of drug X in the treatment of Y" but ultimately opted for the Swiss form, noting with respect to the German form that: "*It is to be regarded as unfortunate that the appellant in the Hydropyridine case withdrew an appeal to the English Courts against a refusal of the United Kingdom Patent Office to grant a patent for the same invention. The decisions of the national courts of two Contracting States tending in the same direction might have had great weight…Indeed if other superior courts in Contracting States show that they are prepared to follow the Federal Court of Justice, in respect of national patent applications, the way may be open for the EBA to reconsider the question so far as the EPO is concerned.*" Although there is no doubt that Swiss form claims were always viewed as a compromise in order, as Jacob LJ put it, "*to steer clear of two obstacles to patentability, namely the requirement of novelty and the ban on methods of treatment of the human body by therapy.*", one wonders if the EBA would have regarded Swiss form claims as providing an appropriate solution, had they been able to see how such claims would be interpreted by the English Patents Court just over 30 years later?

There had not been many cases on the construction of Swiss form claims in the UK until relatively recently. The early decision in **Wyeth** [1985] confirmed that such claims were process claims and the history and purpose of such claims was set out clearly in **Actavis v Merck** in 2008 from which the above quotation from Jacob LJ is taken. However, the last few years has seen a notable increase in the number of disputes concerning such patents, which is not surprising given their potential value. In the **Ranbaxy v AZ** case in 2011, Kitchin J considered the infringement of a patent containing various sets of claims including Swiss form claims and concluded not only that the skilled person would be taken to know basic drafting conventions used to frame a patent but also that such claims should be construed purposively such that "*Use of X in the manufacture of a drug for the treatment of Y*" should be taken as meaning "*Use of X in the manufacture of a drug* ***containing X*** *for the treatment of Y*" in the circumstances before him. In effect Kitchin J recognised that the literal interpretation of the claim would lead to some potentially unintended

results and thus construed the claim to avoid this.

Over the past few years, there have been glimpses of judicial thinking on other aspects of the construction of the claims. In the **Actavis** case, Jacob LJ held, obiter, that the claims were directed to the manufacturer and did not "touch the doctor". More recently in **Hospira v Genentech** (No.1), Birss J held that "for" in the context of a second medical use claim meant "suitable and intended for" and in the second **Hospira v Genentech** case, the same Judge observed informally that it was not in fact settled whether Swiss form claims were product or process claims. At the same time, more and more attention has been given in IP think-tanks outside of the courts to second medical use patents and skinny-labelling i.e. the process whereby a generics company carves-out a patented indication from the list of indications that its medicine is authorised to be used for. In an ideal world, this would enable the generic medicine to compete with the branded medicine in relation to non-patented indications whilst leaving use in the patented indication to the branded medicine exclusively. However, problems arise when the generic medicine, which will inevitably be cheaper than the branded medicine is used for the patented indication. In the UK, the problem is exacerbated by the following: (i) the government strongly encourages prescriptions to be written by INN and not by brand (ii) the prescription will generally not set out the indication for which the medicine is to be used and (iii) it is usually financially advantageous for pharmacists to dispense the cheapest possible medicine to fulfil any given prescription. The IP think-tanks have generally concluded that the solution to the problem ultimately lies in changes to the regulatory framework but that it would not be appropriate for a generic manufacturer to be able to turn a Nelsonian blind eye to the situation where its product is being used "cross-label" for the patented indication.

The issues finally came to a head in an application made by Warner-Lambert for interim relief in respect of Actavis' generic pregabalin medicine known as Lecaent. Pregabalin is the active ingredient in Warner-Lambert's Lyrica medicine which is authorised to treat several conditions. Compound patent protection for pregabalin expired in 2013 but Warner-Lambert has a second medical use patent with Swiss form claims to the treatment of pain which, on the evidence, probably amounted to around 50% of the sales in the UK.

The relief requested by the patentee was unusual in that it was applying for a mandatory injunction forcing Actavis to take various steps to try and preserve the Lyrica market for pain pending the outcome of the trial scheduled for June 2015. Both sides had already taken (or agreed to take) a number of steps to try and prevent the dispensing of Lecaent for pain. The interim measures requested from the court included a requirement for notices to be placed on Lecaent's packaging highlighting that it should not be dispensed for pain, and for conditions to be included in any agreement for the supply of Lecaent to the effect that reasonable endeavours should be used not to dispense it for treatment of pain. Having heard no fewer than three days of argument on the application of the **American Cyanamid** test to the unusual facts of the case, Arnold J found in favour of the Defendants on the grounds that: (i) Warner-Lambert did not have an arguable case of infringement by Actavis of its pain patent and (ii) even if there was an arguable case of infringement, the balance of the risk of injustice favoured the refusal of the relief sought.

The decision is of interest for a number of reasons, including the Judge's comments on the construction of Swiss form claims. Having considered UK case law on second medical use patents some of which is summarised above, Arnold J 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). Arnold J did not consider that intention to sell with knowledge that the product would be used for

the patent protected indication was sufficient for direct infringement under Section 60(1)(c) of the UK Patents Act – the manufacturer must have a subjective intention that its product will be used for the protected indication. Given this construction, the Judge felt that there was no serious issue to be tried as Warner-Lambert had not relied upon any allegation of subjective intention on the part of Actavis. The also noted that Warner-Lambert had originally claimed for indirect infringement of its patent pursuant to Section 60(2) of the Act but that: "*Counsel for Warner-Lambert did not press this claim. He was right not to do so. There can be only be infringement under section 60(2) if there can be infringement by the person supplied or by a user further down the chain of supply (although it is not necessary for there actually to be an infringing act). This is not the case here, since no wholesaler or pharmacist will use Lecaent to prepare a pharmaceutical composition.*"

Arnold J nevertheless went on to consider the balance of convenience and noted that, whilst it would be difficult to quantify Warner-Lambert's loss if no order was granted, the effect of the relief sought would be to deter pharmacists from dispensing Lecaent for any indication and as such Actavis may be excluded from the non-patented market. The Judge felt that granting the relief "*would create a greater risk of injustice than refusing it*".

In his judgment, Arnold J observed that the best solution to the problem of cross-label use would be to try and ensure that doctors prescribing pregabalin for the treatment of pain did so by reference to the brand name Lyrica rather than by INN. He felt that there was a reasonable prospect that guidance could be issued by the NHS to encourage prescription by brand for pain and that he "*would encourage them to consider doing so*".

It is a matter of public record that Warner-Lambert have applied for permission to appeal this decision and, even if the Judge's findings on balance of convenience are not disturbed, it would seem that his findings on the construction of Swiss form claims should be considered by an appellate court as the finding that subjective intention on the part of the manufacturer is required means that Swiss form claims will often be very difficult, if not downright impossible, to enforce in the UK against a skinny-label generic. This is particularly the case where, as is often the case with medicines, the active ingredient is made by one company in one country which is then processed into the dosage form by another company somewhere else and boxed with the PIL somewhere else and so on. It seems wrong in principle that subjective intention (as distinguished from knowledge) is required. When AIPPI considered the issue, it resolved that each case should be assessed on a case-by-case basis including the knowledge of the uses of the pharmaceutical by the alleged infringer or whether such uses were obvious in the circumstances. Additionally, is it right that Section 60(2) would be in play if the product was, for instance a lyophillisate which was reconstituted by a healthcare professional shortly before administering to the patient, but not for a tablet or capsule?

The problem over the interpretation of Swiss form claims will eventually go away as they are replaced by claims framed in the so-called "EPC 2000" format of "X for use in the treatment of Y". Following **G2/08** It has been compulsory to use EPC 2000 claims in patent applications filed in the UK since May 2010 and Arnold J made it clear that his decision in Lyrica does not touch on this area. In **T1780/12** the EPO has already confirmed that EPC 2000 claims and Swiss form claims have a different scope. However, allowing for SPCs, Swiss form claims will be around until 2035 and the author expects that there will be more jurisprudence in this area over the next 20 years. Indeed earlier this week, the Dutch Court of Appeal issued a decision touching upon this area which my friend at Brinkhof will comment upon in the coming days.

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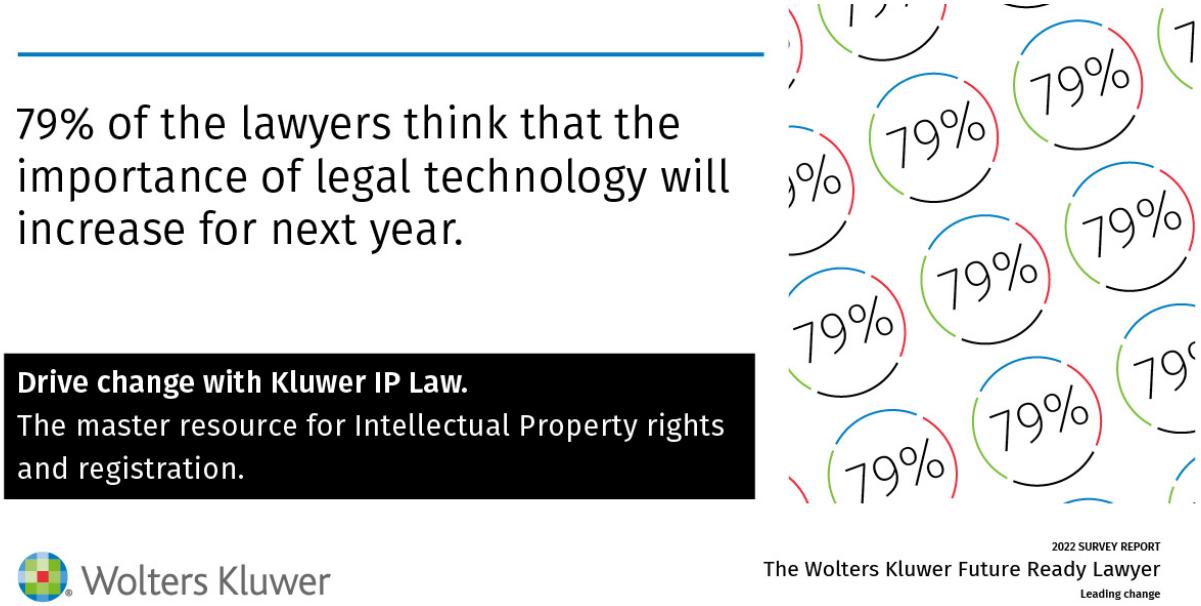

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