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English courts tackle Swiss claims and off-label use

The English courts have recently considered a question pivotal to the perceived value of Swiss-type claims: to what extent can such claims be used to restrict off-label use where other uses of a drug are no longer protected by a patent?

STOP PRESS

This article was written and published on Wednesday 4th February 2015. On 6th February, a further decision in the case was handed down by Mr Justice Arnold. The 6th February decision considers, amongst other issues, Warner-Lambert's application to amend its pleading concerning section 60(1)(c) to include an allegation of subjective intent against Actavis. Permission to amend has been granted, though it has not been accepted that the pleading discloses reasonable grounds for such an allegation. The case will proceed to trial in June 2015 on the basis that it is important for the court to consider the facts before trying to determine the law. We will write again, once the trial has happened.

A judgment handed down on 21st January 2015 by Mr Justice Arnold, a specialist patent judge in the English Patents Court, provided guidance on the scope and enforceability of "Swiss-type" second medical use claims[1]. In particular, he considered a question pivotal to the perceived value of Swiss claims, namely, to what extent these claims can be used to restrict "cross-label" (referred to in the judgment as "off-label") use where other uses of a drug are no longer protected by a patent. Whilst the decision relates to interim relief, it is some of the clearest guidance from the English courts to date on the scope and enforceability of Swiss claims, although it is expected to be appealed.

Background to the dispute

The drug in question in this dispute is pregabalin, a blockbuster drug marketed by Warner-Lambert (part of the Pfizer group) under the brand name Lyrica®. Lyrica® is marketed for three separate indications: epilepsy, generalised anxiety disorder (GAD) and neuropathic pain. Although patent protection and data exclusivity for pregabalin per se have expired, Warner-Lambert owns a second medical use patent relating to the treatment of neuropathic pain, which will not expire until 2017. It is this second medical use patent which is the subject of litigation between Warner-Lambert and various generic companies, including Actavis.

In view of the loss of other patent protection and data exclusivity for pregabalin, Actavis and other generics companies have applied for marketing authorisations for their own pregabalin products. However, these marketing authorisations will be limited to refer to epilepsy and GAD only, and they will not refer to neuropathic pain, the patented indication. Medicinal products authorised in these circumstances are often referred to as "skinny label" products[2].

In this case, Warner-Lambert's concerns arise from the procedures typically followed by healthcare professionals in the UK when prescribing drugs. Most prescriptions are written "generically", meaning that the dispensing pharmacist is free to give branded or generic versions of a drug to patients. Additionally, the vast majority of prescriptions do not specify the indication for which the drug has been prescribed. With this in mind, and given the incentives for pharmacists to dispense the least expensive form of a drug, there is a risk that pharmacists will dispense generic drugs to patients for patented indications. In the case of pregabalin, Warner-Lambert's concern is that pharmacists will dispense generic pregabalin for patients who require treatment for neuropathic pain, and that this "off-label" use will infringe the patent.

Correspondence between the parties

Actavis informed Warner-Lambert of plans to sell its skinny label product under the brand name Lecaent® and of its view that this would not infringe the second medical use patent. Actavis also launched proceedings seeking revocation of the patent, to clear the way for a full-label product including all indications. However, Actavis acknowledged that it would not be able to proceed with a full-label product launch until after the revocation proceedings had concluded.

1. That is, claims of the format "Use of X in the manufacture of a medicament for the treatment of disease Y" which were first introduced by EPO Enlarged Board of Appeal decision G 5/83.

2. Directive 2001/83, Article 11, allows such "skinny labels" for generic products.

In further correspondence between the parties, Actavis agreed to take steps to ensure that Lecaent® was not prescribed or dispensed off-label for the treatment of neuropathic pain, the patented indication. These steps included writing to Clinical Commissioning Groups, Health Boards, superintendent pharmacists and NICE (the UK public body that publishes guidance on health care issues), stating that Lecaent® should not be prescribed or dispensed for treating neuropathic pain. Warner-Lambert did not deem that these steps were sufficient and sought interim relief for tighter restrictions on the launch of the skinny label product, in particular for notices to be applied to the external packaging stating that the product was not authorised for and should not be dispensed for the treatment of pain. Warner-Lambert also sought contractual obligations on Actavis's supply agreements with pharmacists and distributors. These additional restrictions were the subject of Warner-Lambert's application for interim relief and the court's judgment.

The judgment

The judge considered that there were two main questions to be tried. The first question was whether it was seriously arguable that Actavis would infringe the second medical use patent unless it took positive steps to prevent the off-label use. The second question to be resolved was what steps, if any, Actavis should be obliged to take pending the full trial on infringement, if it was determined in the first question that there was a serious issue to be tried.

On the question of infringement and interpretation of the second medical use patent, it was common ground between the parties that the Swiss claims were process claims and that any infringement would be by virtue of dealing in a product obtained directly by means of the process, under section 60(1)(c) of the UK Patents Act 1977. It was also common ground that the purpose limitation "for treating neuropathic pain" in the Swiss claims should be interpreted as meaning "suitable and intended for treating neuropathic pain" in line with the approach taken in *Hospira UK Ltd v Genentech Inc.* [2014] EWHC 1094 (PAT). The issue which divided the parties was whether Lecaent® was a product intended for treating neuropathic pain. There were two points of disagreement between the parties.

Firstly, it was necessary to address the question of whose intention is relevant in these circumstances. Secondly, and more fundamentally, it was also necessary to consider what was meant by "intended" in the context of a Swiss claim.

Whose intention is relevant?

Warner-Lambert's position on the first point was that the relevant intention was that of the person disposing of the drug (i.e. the pharmacist or distributor), rather than the manufacturer. However, the judge disagreed, relying on the fact that the Swiss claim is a claim to a process of manufacture and must therefore be directed to the person carrying out the process, i.e. the manufacturer. In reaching this conclusion, the judge relied on the fact that the claim was not a product claim to the pharmaceutical composition itself, and so was not directed to the person who disposes of the product. These comments suggest that a different conclusion would have been reached if the patent contained EPC 2000 second medical use claims, which are typically thought of as being product rather than process claims. These comments echo recent EPO Board of Appeal jurisprudence (T 1780/12) also referred to by the judge, holding that EPC 2000 medical use claims and Swiss claims have a different scope of protection (see our previous article on this topic here).

The meaning of "intended"

On the question of what is meant by "intended" in these circumstances, Warner-Lambert's view was that sufficient intent would be present if Actavis intended to sell Lecaent® and knew that pharmacists were likely to dispense it off-label for treating neuropathic pain. Again, the judge disagreed with Warner-Lambert, holding that the word "for", in Swiss form claims, imports a requirement of subjective intention on the part of the manufacturer that the medicament will be used for treating the specified condition. Such subjective intention could be established by evidence, such as reference to the patented indication on the packaging of a drug, or promotion of the drug for off-label use by the manufacturer. However, since Warner-Lambert did not rely on any subjective intention on Actavis's part and no evidence of the kind was produced to support such an allegation, the judge dismissed the application for interim relief as failing to raise a serious issue to be tried. In case he was wrong on the substance and there was a serious issue to be tried, the judge went on to consider whether the balance of injustice favoured granting or refusing the injunction. However, Warner-Lambert was also unsuccessful on this ground, with the judge deciding that the risk of injustice against Actavis if the injunction was granted was greater than the corresponding risk to Warner-Lambert if it was not granted.

The English Patents Court has provided guidance, in some of the clearest terms yet, on the scope of Swiss claims and against whom and to what extent these claims can be enforced. This judgment seems likely to be one in a series of decisions in connection with this product. Warner-Lambert has already indicated it will apply for permission to amend its case to plead subjective intent, whilst Actavis have stated that they intend to apply for a summary judgment in view of the favourable comments on infringement. It is also likely that Warner-Lambert will apply for leave to appeal this interim decision, and so more twists and turns in this dispute are to be expected.

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