Swiss claims – Full of holes?

Recent judgements raise questions regarding the enforceability and construction of so-called Swiss-type claims.

Two recent UK judgements involving pharmaceutical manufacturers Warner–Lambert Company LLC and Actavis *et al* have raised questions regarding the enforceability and construction of so-called Swiss-type claims. It would seem that Swiss-type claims, which protect second medical uses of known pharmaceutical compositions, could potentially provide only very limited protection in the UK.

Swiss-type claims – those that define a second medical use with the wording *"use of substance X for the preparation of a medicament (or pharmaceutical composition) for treating indication Y"* – have since been superseded by revised legislation in the EPC 2000 which permits second medical uses to be protected by the wording *"product X for treating indication Y"*. The biggest difference is that a Swiss-type claim is a process, and the other is a product claim, the infringement of which are covered by different subsections of the UK Patents Act 1977. However, many patents containing Swiss-type claims are still in force, and as the scope of these claims differs from the new EPC 2000 type second medical use claims, the recent judgements could have a far reaching impact for years to come.

Background

Warner-Lambert Company, LLC ("Warner-Lambert") are part of the Pfizer group. They make a drug called Lyrica™, the generic name for which is pregabalin. The initial product patent covering the drug has now expired; a second patent, covering the use of pregabalin in Swiss-type form for treating pain (and also more specifically neuropathic pain) is still in force. The defendants (collectively referred to as Actavis) have produced a generic version of pregabalin and are seeking a marketing authorisation to cover the drug for use as an anticonvulsant and as a treatment of generalised anxiety order ("GAD"), which were the initial therapeutic indications approved for pregabalin. Their marketing authorisation does not refer to the treatment of pain. Since the generic marketing authorisation does not cover the full range of approved therapeutic indications, it is commonly referred to as a "skinny label". Furthermore, Actavis and a further generics company, Mylan, are seeking the revocation of the second patent.

Warner-Lambert are claiming infringement of their second patent and have sought an injunction against Actavis, predominantly to prevent generic forms of pregabalin being prescribed as an analgesic.

Pregabalin is big business. It is Pfizer's biggest selling drug with global sales of £3 billion – and £200 million in the UK alone. Prescriptions have risen by 53% between 2011 and 2013. The latest data suggests that 54% of prescriptions in the UK for pregabalin were as an analgesic and 44% specifically for neuropathic pain.

Neuropathic pain stems from neuronal damage, and is quite different from inflammatory pain. Non-steroidal anti-inflammatory drugs such as paracetamol would be ineffective for the treatment of neuropathic pain. In the first instance, the drug amitriptyline is provided as treatment, and if that and other drugs fail, pregabalin is prescribed. The difference in price is 11p versus £2.30 a tablet, though pregabalin is often effective in cases where amitriptyline is not, so the outcome makes it worthy of prescription.

When drugs are prescribed in the UK, normally the prescription lists only the generic name of the drug, and not the indication for which it has been prescribed; patient

confidentiality being a major rationale for this. The pharmacist will not know what the drug is for and will invariably reach for the cheaper non-branded version, which is what they are encouraged to do. Furthermore, due to the way the drug is priced by the NHS Drugs Tariff, a pharmacist often has a commercial incentive to prescribe the generic as opposed to the branded drug.

Warner-Lambert wanted a range of outcomes from the injunction, for example that Actavis' drugs are labelled not to be used for pain, and that doctors only prescribe their branded product rather than the generic drug when it is to be used for treatment of pain. Actavis have restricted their marketing authorisation to epilepsy and GAD, and have offered to write to the various health authorities and pharmacies.

In the first instance case, the Judge considered that the best outcome would be that doctors prescribed Lyrica for pain, rather than the generic name pregabalin, however it was entirely out of Actavis' hands whether or not this actually happens.

But is Warner-Lambert's claim for infringement a serious issue to be tried?

Under section 60(1)(c) of the UK Patent Act 1977, it is an infringement *to "…offer or dispose of any product obtained directly by means of [the claimed] process"*. Swiss claims are process claims, and Actavis make a product using a process, but do they manufacture the product *"for treating (neuropathic) pain"*, as covered by the claims of the patent. It is established case law that *"for"* is interpreted as meaning *"suitable and intended for"*, and furthermore that such claims are aimed at the manufacturer and not the doctor that prescribes or the pharmacist that dispense the drug. Only Actavis could be the infringer under this section.

There is no question that Actavis make a drug that is suitable for treating pain, but is it *intended* for treating pain? Whilst it was foreseeable that the drug could likely be prescribed *for* pain, was there an *intention* on Actavis' part that this be so? The judge held that the "for" in Swiss-claim language 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. As this was not considered to be the case, the Judge held that there was no question to be tried, and furthermore, if he was wrong, that if any injunction were granted, it would cause more harm to Actavis than the harm that would befall Warner-Lambert if it were not granted. As such, interim relief was denied.

The two parties returned to court. On this occasion, Warner-Lambert wished to amend their particulars of infringement to plead a case of subjective intention, and Actavis requested that the claim for infringement be struck out or summary judgement be provided.

In the meantime, the Judge had happened upon two further pieces of evidence – one from the Pharmaceutical Services Negotiating Committee representing NHS pharmacy contractors requesting that Lyrica be prescribed by name for pain, and one from the North of Tyne Area Prescribing Committee which basically stated that there is no clinical reason not to provide the generic version, and that was that.

The case for subjective intention was heard – Warner-Lambert complained that 54% of prescriptions of pregabalin were for pain, the majority of prescriptions were written generically and that 95% of prescriptions do not state the indication for which it is prescribed. Actavis should know full well that their drug will be prescribed for pain. Actavis contend that they have gone out of their way to put in place measures that would prevent this happening. The judge agreed this does not amount to an intention for pregablin to be prescribed for the treatment of pain, but merely a foreseeable consequence. As such the Judge thought there was no subjective intention… but also stopped short of deciding that the case for infringement should be struck out in case his interpretation that Swiss-type claims require substantive intention prove to be wrong in a higher court, where this developing area of law ought to be established.

Interestingly a similar case tried in the Dutch courts (Novartis v Sun) concluded that Swiss claims be interpreted as product claims, thought the facts of that case were different in several important aspects.

Discussion

If the interpretation of Swiss-type claims requiring subjective intention becomes precedent in the UK, the proprietors of patents containing such claims will be greatly disadvantaged. The generic manufacturer will merely need to demonstrate that there is no subjective

intent for the drug to be used for a patented indication, even though its use for the patented indication is an inevitable consequence of the prescribing process.

Post-script

Warner-Lambert took this case one step further and obtained a **High Court Order** against the NHS, forcing them to issue guidance on the prescribing of pregabalin. Essentially, the NHS will now issue guidance that pregabalin should only be prescribed for the treatment of neuropathic pain under the brand name Lyrica. Further, where dispensing pregablin, and the pharmacist knows it is for pain, they pharmacist should dispense Lyrica. Quite whether this guidance will remain effective remains to be seen.

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Contact

For more information please contact Chris Burnett via email at cjb@aathornton.com or your usual A.A Thornton & Co. advisor.

For general information please visit: **www.aathornton.com**

Partners

Vanessa Lawrence
vabl@aathornton.com

Ian Gill
isg@aathornton.com

Martin Hedges
mnh@aathornton.com

Craig Turner
crt@aathornton.com

Rachel Havard
rsh@aathornton.com

Adrian Bennett
arb@aathornton.com

Mike Jennings
mjj@aathornton.com

Emily Cottrill
eehc@aathornton.com

Lawrence King
llk@aathornton.com

Associates

Nick South
ngs@aathornton.com

Heather Donald
hrd@aathornton.com

Sarah Darby
smd@aathornton.com