ENGLISH COURT OF APPEAL RULES ON THE CONSTRUCTION OF SWISS FORM PATENT CLAIMS IN *WARNER-LAMBERT v ACTAVIS*

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The Court of Appeal of England and Wales has ruled that no subjective intent is required for the infringement of a patent claim in Swiss form. The much-awaited guidance from a higher court on the construction of Swiss form claims is likely to influence the approach taken by courts in other European Patent Convention states.[1]

Summary

The Court of Appeal's decision of 28 May 2015 in *Warner-Lambert v Actavis*[2] confirmed Mr Justice Arnold's decision not to award interim relief with regard to Warner-Lambert's claim for infringement of its Swiss form claim. Arnold J had concluded that, following the *American Cyanamid* approach, the 'balance of justice' favoured not granting interim relief, and the Court of Appeal agreed.

Following the Court of Appeal's decision, it would seem that interim relief will only be available from the courts in the United Kingdom to restrain infringement of a 'second medical use' patent where the facts are unusually stark. In general, where a generic pharmaceutical company has 'carved out' a patented indication from its label and may legitimately sell its medicine as approved for other 'indications', it will not be prohibited from selling the medicine in the United Kingdom.

Further, there are questions as to the availability of injunctive relief to restrain infringement, and also as to the extent of damages that will be awarded, after a finding of liability for patent infringement where the infringing medicine may legitimately be sold for a non-infringing purpose.

However, the Court of Appeal's rulings on the construction of the Swiss form claim in issue will be welcomed by the patentee in this case, by the innovative pharmaceutical industry more generally and by lawyers in the United Kingdom and other European Patent Convention (EPC) jurisdictions grappling for guidance on the construction and enforceability of such claims.

The decision would also seem to pave the way for healthcare bodies, including the National Health Service (NHS), to be found liable for patent infringement where requisite knowledge is present. This may encourage such bodies to improve their mechanisms and guidance on the prescribing and dispensing of medicines so as to enable the rights conferred by second medical use patents to be respected and complied with. In the Court of Appeal, Lord Justice Floyd gave the only reasoned judgment. His key finding is that in a Swiss form claim (that is, 'use of X in the manufacture of a medicament for the treatment of Y'), the word 'for' does not mean 'suitable and intended for' as held by Arnold J at first instance. It requires knowledge (and for this purpose constructive knowledge is enough) or reasonable foreseeability, of ultimate intentional use for the claimed medical indication. There is no requirement that the manufacturer has that specific intention or desire himself and therefore no evidential burden on the patentee to demonstrate such intent.

Background

Warner-Lambert is a part of the Pfizer group of companies. Its European patent number EP (UK) No. 0 934 061 ('the Patent') claims the '[u]se of [pregabalin] or a pharmaceutically acceptable salt thereof for the preparation of a pharmaceutical composition for treating pain'. Warner-Lambert's pregabalin medicine is marketed as 'Lyrica'.

1) See also Brian Whitehead and Stuart Jackson, '*Warner-Lambert v Actavis*: what are the limits of Swiss form claims?' 14(3) *Bio-Science Law Review* at 107 to 114.

2) [2015] EWCA Civ 556.

Warner-Lambert's patents covering the use of pregabalin for generalised anxiety disorder (GAD) and epilepsy had expired. Actavis commenced revocation proceedings against the Patent in September 2014. In the course of subsequent correspondence, Actavis indicated to Warner-Lambert that it planned to launch a generic pregabalin medicine (called 'Lecaent') in the United Kingdom with a 'skinny label'. A 'skinny-label' medicine is one in which a patented indication is not included in, or is 'carved out' from, the list of medical indications for which the medicine is listed as authorised (in this case generalised anxiety disorder and epilepsy) in the Summary of Product Characteristics (SmPC) and Patient Information Leaflet (PIL).

Warner-Lambert sought interim relief from the court. It could not object to supplies of Lecaent going to patients who needed pregabalin for non-patented (that is, non-pain) indications. The relief it sought was not in the conventional prohibitive form (that is, restraining sale). Instead, Warner-Lambert sought to impose obligations upon Actavis to give notice to distributors, pharmacists and healthcare bodies that Lecaent was not authorised for pain, and/or that it should not be prescribed or dispensed for the treatment of pain. Warner-Lambert also sought to impose contractual obligations upon the supply chain to use reasonable endeavours to achieve this.

The Patents Court Refused to Award Interim Relief

In the Patents Court, Arnold J considered Warner-Lambert's application for interim relief in accordance with the approach laid down by the House of Lords in *American Cyanamid v Ethicon*.[3] He found on the evidence before him that:

> *It is foreseeable that pharmacists will dispense the generic version of the drug for patients who have in fact been prescribed the drug for treating the patented indication, unless positive steps are taken to prevent this.*

However, following his construction of the Swiss form claim in issue, he concluded that Warner-Lambert had shown no serious question to be tried on direct or indirect infringement of the Patent. He also concluded that the interim relief sought was not justified on the 'balance of justice'. For both reasons, he refused Warner-Lambert's application.

The Patents Court Struck Out Part of Warner-Lambert's Pleaded Case

If Warner-Lambert had shown no serious question to be tried on infringement, how could it succeed with its main claim?

In view of his construction of the Swiss form claim in issue, Arnold J did not think that Warner-Lambert could succeed. Shortly after refusing to award interim relief, he struck out Warner-Lambert's claim of indirect infringement under section 60(2) of the Patents Act.

Section 60(2) of the Patents Act provides as follows:

> *Subject to the following provisions of this section, a person (other than the proprietor of the patent) also infringes a patent for an invention if, while the patent is in force and without the consent of the proprietor, he supplies or offers to supply in the United Kingdom a person other than a licensee or other person entitled to work the invention with any of the means, relating to an essential element of the invention, for putting the invention into effect when he knows, or it is obvious to a reasonable person in the circumstances, that those means are suitable for putting, and are intended to put, the invention into effect in the United Kingdom.*

The provision is derived from Article 26 of the Community Patent Convention. As such, the laws of many other European Patent Convention countries contain equivalent provisions. Interestingly, a few days after Arnold J refused to award interim relief to Warner-Lambert, the Court of Appeal in The Hague (Netherlands) decided to award interim relief based on a case of indirect infringement, in a dispute between Novartis and Sun Pharmaceuticals. That dispute also concerned the alleged infringement of a Swiss form patent claim. Construction was not considered in detail but the Dutch court was provisionally satisfied that Sun had indirectly infringed the patent.[4]

3) [1975] AC 396.

4) See Gertjan Kuipers and Bertrand ter Woort, 'Skinny labelling and direct infringement – consider being proactive: *Novartis v Sun*', 14(3) *Bio-Science Law Review* at 115 to 118.

Arnold J was not deterred by the apparent inconsistency that would arise between his strike out and the Dutch court's ruling. His reasoning, essentially, was that Warner-Lambert's claim was to a manufacturing process. Since no party downstream of Actavis was involved in manufacture ('no wholesaler or pharmacist will use Lecaent to prepare a pharmaceutical composition') he thought it was 'hopeless' for Warner-Lambert to contend that Actavis supplied 'essential means' for (later) putting the invention into effect.

Arnold J did, however, allow Warner-Lambert's claim of direct infringement under section 60(1)(c) of the Patents Act to proceed to trial. Section 60(1)(c) prohibits dealings in the product of a patented process. Arnold J still thought there was no likelihood of infringement because Actavis' Lecaent was not, on the pleaded facts, 'suitable and intended for' the patented pain indication. However, since this was a 'developing' area of the law, the better course was to permit the claim to proceed to trial (so that the relevant facts – for example, regarding what Actavis intended – could be determined) and then to deal with the law on any appeal.

Arnold J's acceptance that the word 'for' in the Patent claim language meant 'suitable and intended for', and his ruling that 'intended' required subjective intent on the part of Actavis, underpinned these conclusions.

Warner-Lambert appealed.

Permission to Appeal

The Court of Appeal was persuaded to hear an appeal. A key factor in permission being given was the judge's expressed view of the prospects of the NHS issuing guidance on the prescribing of generic pregabalin medicines. This was relevant to his assessment of the 'balance of justice'.

By the time the appeal was heard, Arnold J had, in fact, made an order requiring NHS England to issue guidance to Clinical Commissioning Groups on the prescribing of pregabalin.

The Court of Appeal's Judgment

In the Court of Appeal, Lord Justice Floyd gave the only reasoned judgment.

Likelihood of Infringement: Arnold J Overruled

On the likelihood of infringement, Floyd LJ went back to first principles. This involved distinguishing two concepts:

(1) the technical subject-matter of the claim (as defined by Article 69(1) EPC); and

(2) the legal rights conferred upon the proprietor under national law by the grant of the patent (expressed by Article 64(1) EPC to be a matter for national law).

After setting out the history of Swiss form claims and the key authorities from the European Patent Office, the English courts, and the courts in Australia, Germany and the Netherlands, Floyd LJ stated that Warner-Lambert's claim was a process claim. This finally settles the status in the United Kingdom of Swiss form claims as process claims, not product claims.

Floyd LJ explained that the skilled person would understand the technical subject-matter of the claim to be concerned with the ultimate end use of the medicament, from which it derived its novelty. The therapeutic treatment was new because, and only because, it was carried out with the *intention* of producing the new therapeutic effect. (The prior use of the compound may have in fact produced the effect, for example if a patient taking it for GAD or epilepsy was at the time experiencing pain as well.) It is the intention for which the compound is administered which is at the heart of the invention.

Against that background, the skilled person would understand the word 'for' (that is, 'use of X in the manufacture of a medicament *for* the treatment of Y') in the claim to be providing a link between the act of manufacture using pregabalin and the ultimate intentional use of the drug by the end user to treat pain.

The critical issue for the court was to decide what was sufficient to constitute that link.

The Court of Appeal ruled that (contrary to Arnold J's conclusion and the agreement of the parties before him) the answer was not to read the word 'intended' into the claim

language. Floyd LJ explained that a search for the appropriate meaning of 'intention' is 'likely to throw one off the scent'. Rather, the link was '*foreseeability that the drug will intentionally be used for the patented invention*'.

This did not require the manufacturer to have that specific intention or desire himself.

As such, Floyd LJ reasoned that the test has structural similarities to that under section 60(2). Nor does it prevent that which was done before because, before the patent was granted, '*it was not possible to foresee that the product would intentionally be used for treating pain*' (emphasis added). Similarly, prior art manufactured in circumstances when it was not possible to foresee such a result does not cause problems for novelty.

On the other hand, there were problems with requiring subjective intention to effect the link, including the evidential burden on the patentee – exactly where Warner-Lambert had fallen short before Arnold J.

Floyd LJ noted that it was possible to envisage cases where the consequences of construing a Swiss form claim in this way potentially caused unfairness. One example was of an existing manufacturer whose sales increased as a result of the invention the subject of a second medical use patent; another was where, despite taking all steps open to him to avoid prescribing and dispensing for the patented use, the structure of the marketplace prevented this happening.

However, the answer was not to contort the construction of the claim, which describes the subject-matter of the patent pursuant to Article 69 EPC. The better course was to address such situations by tailoring the relief granted, that is, within the second stage of analysis – the legal rights conferred by the patent.

Consequences for Warner-Lambert's Claims of Infringement: Arnold J Overruled

One consequence of this construction of the Swiss form claim in issue is that if the relevant manufacturing process took place within the United Kingdom, Warner-Lambert would have an arguable case on infringement under section 60(1)(b), that is, use of the claimed process. The purposive element regarding use under section 60(1)(b) is, pursuant to the construction of the Swiss form claim, foreseeability – a finding on which has already been made by Arnold J.

Another consequence is that Warner-Lambert has an arguable case on infringement under section 60(1)(c). This section prohibits dealings in the direct product of the patented process. Again, the purposive element is that imported by the Court of Appeal's 'foreseeability' test.

Further, Warner-Lambert also has an arguable case under section 60(2). The Court of Appeal's comments here were rather interesting, indicating a need for a wholesale examination of the provision at the trial. Floyd LJ said:

> … *It may be that the invention is put into effect if pregabalin is manufactured by one person and supplied to another who intentionally uses it for the treatment of pain. In those circumstances, a person who supplies pregabalin with the requisite knowledge (i.e. that prescribed in section 60(2) itself) does provide means suitable and intended to put the invention into effect, albeit by the combination of manufacturer and user, rather than by any one person alone.*

It is worth perhaps remembering that section 60(2) does not refer to the 'claims' of the patent but to the 'invention'. It remains to be seen whether 'manufacture' will be a necessary element for infringement under this provision.

In Floyd LJ's view, the decision of the Dutch court (discussed above) and a decision by a court in Germany, in parallel litigation in which Warner-Lambert was awarded interim relief to restrain indirect infringement of its Swiss form claim, were themselves reason enough not to strike out Warner-Lambert's claim under section 60(2).

The Balance of Convenience

The Court of Appeal's comments on the legal rights conferred upon the proprietor of a patent are relevant beyond the interim relief in issue.

As mentioned above, Floyd LJ noted that the legal rights conferred upon the proprietor are a matter for national law.

Where an existing manufacturer's sales were increased by a later invention of a new therapeutic use, Floyd LJ made it clear that a general injunction prohibiting sale of the product itself would not be justifiable. This may be the case also where the manufacturer was not a prior user, if the grant of an unqualified injunction 'would unfairly prejudice his right to sell the drug for the non-patented indication'.

The reasoning would seem to apply to inventions residing in a second (or subsequent) therapeutic use, whether the claim language is in Swiss form or EPC 2000 'purpose limited product' form (that is, 'X for use in the treatment of Y'). Decisions as to the availability of injunctive relief in such cases will, therefore, be a matter for consideration in the full circumstances of each case, perhaps with injunctive relief being awarded only in exceptional cases.

In the present case, Floyd LJ agreed with Arnold J that the balance of justice favoured not awarding the interim relief sought by Warner-Lambert, even in the watered-down form in which it reached the Court of Appeal. The judge had considered, as had the parties, that the best solution to the problem, at least for interim purposes, was for the NHS to give guidance. In assessing the balance of justice, the judge had correctly assessed (indeed, he had underestimated) how likely it was that such guidance would be issued.

Floyd LJ refused Warner-Lambert permission to adduce evidence that the guidance issued by the NHS thus far has not been effective. This was because the purpose of the appeal was to review the judge's exercise of discretion on the material before him, not to permit a 'free-for-all'.

Comment

It remains to be seen whether Warner-Lambert will be able to maintain the monopoly conferred by its Patent if it succeeds in establishing that the Patent is valid and has been infringed. The trial is scheduled for June/July 2015.

In view of the Court of Appeal's judgment, injunctive relief would seem unlikely or may be very limited in scope. It must also be questioned whether the total profits made by all the parties distributing generic pregabalin medicines in the United Kingdom would meet Warner-Lambert's lost profits caused by the infringements.

So how will the courts protect Warner-Lambert's loss of market exclusivity (for the pain indication) during the term of the Patent (and any Supplementary Protection Certificate)?

Perhaps the most important consequence of the Court of Appeal's decision is the (at least technical) prospect of liability attaching to healthcare bodies (that is, the NHS or parts of it) for infringement of patents with claims in Swiss form. Even though injunctive relief may not prove readily available, the possibility of being ordered to pay monetary relief might, finally, overcome the inertia in such bodies to invest in prescribing and dispensing mechanisms which enable the rights conferred by second medical use patents to be respected and complied with.

Underlying this is the Court of Appeal's long-needed groundwork on the construction of Swiss form claim language. Floyd LJ's clear, concise reasoning underpins an important judgment for patent lawyers and the pharmaceutical industry in the United Kingdom and in Europe.