Obiter dicta – Skinny labels and infringement

A brief summary of what the Supreme Court said about infringement of Swiss-form claims (even though it didn’t need to)


Overview

Incentivising pharmaceutical companies to invest in identifying second and subsequent uses of known compounds is an acknowledged challenge across the pharmaceutical industry. Part of that challenge is ensuring that generics are not excluded from the marketed off-patent indications. Patentees must be allowed to get a return on their investment for their second medical use patent without completely restricting the activities of the generics.

One aspect of this issue that has been under the spotlight in recent years is the infringement of Swiss-form claims. The case we are referring to is, of course, that between Warner-Lambert and generic companies regarding use of generic pregabalin for treatment of pain. In the UK alone, this dispute has delivered 12 judgments, including two from the Court of Appeal and one from the Supreme Court. It has been litigated extensively in several other European jurisdictions and has recently been considered by the CJEU (on which we comment briefly at the end of this review).

The patent was ultimately held invalid so the Supreme Court did not need to address infringement at all. Despite this, the Justices of the Supreme Court went to some lengths to set out their assessment of the correct approach to assessment of infringement of Swiss-form claims which we will review in more detail later in this article. In very brief overview:

• All of the justices rejected the “Objective intention” test formulated by Floyd LJ in the Court of Appeal;
• Lord Sumption and Lord Reed favoured a new “Outward presentation” test;
• Lord Briggs and Lord Hodge preferred “Subjective intention” (echoing Arnold J’s preferred approach at first instance); and
• Lord Mance split the difference, agreeing with the Outward presentation test but acknowledging that subjective factors may be relevant in some cases.
All of the judicial comments on infringement are “obiter dicta” (not binding on the lower courts). The divergent opinions of the judges are likely to have a real impact on how parties argue infringement cases:

- **Generics** will want to rely on the Outward presentation test under which they will argue that a skinny label is sufficient to satisfy this test and avoid a finding of infringement.
- **Patentees** will remain concerned about off-label use and will have to seek to establish the existence of subjective factors that demonstrate the generic knows that their product will be used off-label.

It could be an uphill battle for patentees to show such subjective factors potentially requiring extensive factual evidence and disclosure exercises in future litigation.

**Facts of the case**

The case concerns Warner Lambert’s blockbuster drug, Lyrica (pregabalin). Lyrica is approved to treat epilepsy, generalised anxiety disorder (“GAD”) and neuropathic pain. Patent protection for epilepsy and GAD expired in May 2013. However, Warner-Lambert’s second medical use patent provided protection for treatment of pain until 2016. Following expiry of patent protection for epilepsy and GAD, a number of generic companies obtained marketing authorisations under a “skinny label” for their pregabalin products for treatment of epilepsy and GAD only. A “skinny label” refers to a generic omitting the patented indication from its marketing authorisation application (in this case omitting neuropathic pain).

Warner-Lambert, concerned that generic pregabalin would be supplied off-label for treatment of the patented indication, sought to enforce their second medical use patent.

What is significant in this case is that the originator and generic pregabalin products are approved in the same form and dosage for the patented and off-patent indications. The direct substitutability of the generic for the originator makes widespread off-label use of the generic product arguably more likely. Furthermore, while pregabalin is prescribed by GPs to treat common indications, it is dispensed by high street pharmacies and self-administered by patients who do not necessarily know which drugs are protected in respect of which indications. By contrast, in the cases of hospital-only drugs, drugs administered only by healthcare professionals or biologics, or where drugs are administered by different routes, in different forms or different dosages for the patented and off-patent indications, substitution between indications may be less common and the risk of off-label use may be significantly reduced.

In many respects, this substitutability makes the facts of the pregabalin litigation potentially unusual. Couple to that the fact that the Supreme Court decision specifically addresses Swiss-form claims rather than EPC 2000 claims, and it is possible that in future, patentees will be able to argue that the Supreme Court guidance should not apply. Nevertheless, the level of detail in the approach and deliberation of the Justices makes this case worthy of further note and discussion.

**The claim in question**

The broadest claim of the patent in issue is the following Swiss-form claim:

*Use of (S)-3-(aminomethyl)-5-methylhexanoic acid or a pharmaceutically acceptable salt thereof for the preparation of a pharmaceutical composition for treating pain.*

Swiss-form claims are purpose-limited process claims. The process is the manufacture of a drug to be used for a particular therapeutic indication. In assessing infringement of Swiss-form claims, the lower courts have therefore focused on how to establish what the pharmaceutical composition was prepared for. This has involved assessing the manufacturer’s intention.
This is in contrast to EPC 2000 claims which have replaced Swiss form claims. EPC 200 claims are purpose-limited product claims: “Substance X for use in the treatment of disease Y” (our emphasis added). Infringement of EPC 2000 claims was expressly not considered by the Supreme Court: “EPC 2000 patents give rise to difficulties of their own, some of which are very similar. But this appeal is not concerned with them”.

**Infringement**

The first point to note is that the “guidance” provided by the Supreme Court on assessment of infringement applies to direct (primary) infringement only, not indirect (or contributory) infringement.

In particular, this case concerns infringement under section 60(1)(c) of the UK Patents Act 1977. This section applies to dealings in a product obtained directly by means of a patented process. For Swiss-form claims, the process is manufacture of a medicament for treatment of a given indication. Infringement occurs whenever a person disposes of that product, offers to dispose of it, uses or imports it, or keeps it, whether for disposal or otherwise. The infringer may be, but need not be, the manufacturer. The section also applies to anyone in the downstream generic market, including wholesalers and pharmacists. Liability is strict. Provided that the product has been obtained directly by means of the process, liability extends to subsequent dealings with all and every such product irrespective of knowledge that dealing in the product might infringe. This was a significant factor in Lord Sumption’s reasoning; he was concerned to protect pharmacists from inadvertently incurring liability for patent infringement.

Warner-Lambert argued in the alternative for indirect infringement, based on section 60(2) Patents Act 1977. This section applies where the infringer knowingly supplies to a primary infringer the means essential for putting the invention into effect. Unlike direct infringement, liability is not strict. Indirect infringement requires actual knowledge of the infringer that the means supplied are intended for putting the invention into effect.

### Three options for assessing infringement of Swiss-form claims

**Subjective intention**

At the first instance trial of the case (i.e. after Warner-Lambert’s unsuccessful application for a preliminary injunction), Arnold J held that “intention is a subjective state of mind, but it must be objectively assessed and may be inferred from appropriate facts”. He concluded there was no infringement because it was not foreseeable to Actavis that their generic product manufactured at the time in question would be intentionally administered for the treatment of pain, save in a small number of exceptional cases which he considered *de minimis*.

In the Supreme Court, Lord Briggs and Lord Hodge also preferred “subjective intention” which may be “proved objectively by words, conduct or even inactivity”. This would include a skinny label as well as other factors demonstrating the manufacturer’s actual intention. At trial this would take the form of evidence that the manufacturer intends the product to be supplied for patented use e.g. by volume produced (if much larger than necessary to treat the off-patent indication(s) only), marketing activities and internal documents which show the manufacturer’s decision making process. This could be an onerous, expensive and highly uncertain fact-finding exercise.

**Objective intention**

In the Court of Appeal, Floyd LJ rejected subjective intention, favouring an *objective test*: “Does the manufacturer know (or could it reasonably foresee) that at least some of the medicament will intentionally be used to treat the patented indication?” According to the Court of Appeal “the absence of the patented indication from the label cannot conceivably be sufficient to negative the intention”.

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¹ See [2015] EWHC 2548 (Pat) at para 591
² See [2015] EWCA Civ 556 at para 127
³ See [2016] EWCA Civ 1006 at para 207
The generic manufacturer must take “all reasonable steps within his power to prevent” infringing use. Those steps may include writing to pharmacists and doctors informing them not to prescribe the generic for the patented indication, implementing prescribing software to prevent substitution of the generic for the originator drug, and encouraging doctors to prescribe by brand name rather than international non-proprietary name (“INN”). The steps necessary to satisfy this test would vary according to the facts of each case.

Outward presentation

The Supreme Court unanimously rejected the objective intention test. However, while they agreed what the test is not, between the 5 Justices there was no consistent or majority opinion as to what the test should be.

Lord Sumption has given us the “outward presentation test”. He considered (and Lord Reed agreed) that what matters are the physical characteristics of the product as it emerges from the manufacturing process. This includes the dosage, formulation, packaging and labelling. In short, as long as the manufacturer ensures that the patented indication is absent from the product the product will not infringe – a “skinny label” is enough to avoid infringement.

This test has the advantage of certainty for third parties but it leaves patentees exposed when it comes to seeking to protect their patented market in situations where there is a significant risk of off-label prescribing as it does not require any of the additional steps such as those described under the Court of Appeal’s test.

Lord Sumption and Lord Reed wanted to shut the door on trying to determine the manufacturer’s state of mind for assessment of primary infringement.

Lord Mance agreed that outward presentation was relevant to the test, but left open the possibility that subjective factors may be relevant in some cases.

Skinny labels in practice

For a skinny label to be effective, in this case, only pregabalin as Lyrica (as mentioned above, the brand name for the patentee’s pregabalin product) should be dispensed for treatment of the patented indication, neuropathic pain but either Lyrica or the generic may be dispensed for treatment of epilepsy and GAD. But what happens in the real world?

In the UK, the vast majority of prescriptions are written generically, i.e. the doctor specifies the drug’s INN (in this case “pregabalin”) rather than brand name. In the hands of the pharmacist, a prescription saying “pregabalin” may be dispensed as either Lyrica or the generic. The pharmacist will not know the indication for which the product is to be administered.

The steps necessary to satisfy the objective intention test such as informing pharmacists about the patent rights would not enable pharmacists to avoid dispensing for the patented indication.

In rejecting the objective intention test, the Supreme Court was particularly concerned to protect pharmacists from dispensing a drug for the patented indication and thereby being exposed to strict liability for patent infringement in circumstances where they do not have the information necessary to avoid infringement.

Formalisation of the skinny label?

On a closely related point, the question of the effect of a skinny label relating to pregabalin was referred by the Dutch court to the CJEU. The CJEU confirmed that the European legislation that gives rise to the ability for a generic to apply for a skinny label strictly limits the marketing authorisation to the off-patent uses. It confirms that the generic is not licensed to produce and sell the patented products for the patented indications.

*See [2016] EWCA Civ 1006 at para 208*
Article 11 of 2001/83 provides that:

“For [abridged authorisations], those parts of the Summary of Product Characteristics of the reference medicinal product referring to indications or dosage forms which were still covered by patent law at the time when a product at the time when a generic medicine was marketed need not be included.”

A type 2 variation will be needed by the generic applicant to include indications which were previously protected by second medical use patents. This is helpful clarity for patentees on the legal status of generic marketing authorisations. It may enhance argument that a skinny label is all that is required to avoid infringement but the CJEU opinion does not tackle the possibility of cross-label prescribing or any points on infringement as these are national issues.

How might this play out in future litigation?

If a case on similar facts were to start tomorrow, the High Court would not be bound to apply the outward presentation, objective intention or subjective intention tests. Although the unanimous rejection of the objective intention test by the Supreme Court may make that test less likely to be adopted, it remains unclear precisely how the Court would approach allegations of infringement or indeed the lengths that a generics must go to, to put themselves in the best possible position to avoid a finding of infringement.

One thing that does seem to be clear is that the UK court would look closely at the factual scenario. The UK approach to disclosure does mean that it is very possible that the Court will look behind a simple request for a skinny label/MA.

How the question of infringement of Swiss-form claims might be decided in future may well also depend on which judge hears the case. While Arnold J remains in the High Court he might return to his own preferred subjective intention test. Floyd LJ, who formulated the objective intention test remains in the Court of Appeal. Lord Kitchin and Lady Arden agreed with the subjective intention test in the Court of Appeal interim hearing, and both now sit in the Supreme Court. Lord Sumption and Lord Mance have retired.

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