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Lyrica in the Supreme Court: Broader Lessons for Pharmaceuticals

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Darren Smyth – Lyrica –The Effect of the Litigation on Pregabalin Prescribing

Prescribing practices in the UK are complex. Doctors are not bound by the authorised indication of a drug. Although guidance states that doctors should not prescribe off-label unless there is a medical reason, they are encouraged to prescribe generically. Prescriptions do not usually indicate the condition, and although pharmacists must dispense the branded version of the drug if the prescription specifies this, if the generic name is prescribed the pharmacist can dispense any brand or generic even if the generic has a 'skinny label'. This creates a situation in which there is no link between the condition the patient is suffering from, and the form of the medicine which the patient receives. The heart of the problem is that the claim requires the drug and the indication, but in our current system the drug and indication do not appear together.

Pfizer attempted to change this prescribing behaviour by seeking a court order against NHS England requiring the NHS to issue guidance to Clinical Commissioning Groups ("**CCGs**") that pregabalin should be prescribed as Lyrica to treat pain. The order was granted. Mr Justice Arnold at first instance supported the approach of separating the patented and non-patented market by writing prescriptions for the patented indication by reference to the brand name.

This approach, however, assumes that doctors will obey instructions issued by the NHS under a court order. This is not what transpired. Data presented from the Centre for Evidence-Based Medicine demonstrates that doctors were unwilling to abandon generic prescribing for patent reasons. Although prescriptions for Lyrica increased, the number was very far off reaching the 70% expected if Lyrica was specified on all prescriptions for pain. Doctors were, however, willing to alter prescribing behaviour for budget reasons as evidenced by a rise in prescriptions of other 'branded generics' whose manufacturers had arrangements with individual CCGs offering a lower reimbursement price for their drug.

Further data exposes varying trends of compliance by doctors in different regions. This variance is likely due to differing policy decisions at the Commission level as to how to act on the court decision and instruct doctors.

This discussion poses a question of whether the cross-undertaking in damages given by Pfizer in favour of the NHS should be enforced. Prior to expiry of the patent, the

categorisation of pregabalin meant that the reimbursement price was set at the higher Lyrica price whether Lyrica or another brand was dispensed. During the period the court order was in force, the excess prescribing cost (calculated from the difference in price between Lyrica and the generic) was approximately £500 million. However, proving quantifiable loss is more complex. For example, when a generic was dispensed against a generic prescription, the pharmacist profited as it was possible to buy unbranded pregabalin cheaper than Lyrica whilst still being reimbursed at the Lyrica price. When a pharmacist makes excess profit, the NHS will compensate this by reducing the pharmacists' funding, hence some profit ends up back with the NHS. The excess prescribing cost is also partly due to NHS policy as a lower reimbursement price for generics could have been set if the NHS had categorised pregabalin differently. This analysis raises some interesting questions, and any damages claim would undoubtedly be fascinating.

David Rosenberg – Lyrica – The infringement issue

Attempting to outline a test for infringement raises a complex problem, namely, how can the patented market be protected while giving access to the non-patented market? Conflicting policy considerations must be addressed in order to obtain a balanced solution.

In its submissions, Warner-Lambert advocated an objective test for infringement of whether it was foreseeable to the generic manufacturer that its product would be used for the patented indication. It proposed the fall back that if the generic took all reasonable steps to prevent the product going to the patented use it would be absolved from liability. Actavis advocated a subjective test in that the generic must be making the product to target the patented use. Both tests, therefore, involved an element of intent.

At first instance, the subjective test was applied. The Court of Appeal, including Floyd LJ and Kitchin LJ, ruled that foreseeability creates required intent. However, this is negated where the manufacturer takes all reasonable steps to prevent use for the patented indication. Both lower courts, therefore, advocated for the relevance of intent in deciding the matter of infringement.

<u>The Supreme Court's view</u>

The Supreme Court discussed infringement in detail, albeit obiter as the patent was found to be invalid. Lords Sumption and Reed rejected any intent based test. They highlighted a problem with the subjective intention test in that if, as is the case for a Swiss form claim, the intention of the manufacturer is relevant, all parties downstream, such as the pharmacist, may be liable for the acts of the manufacturer. As downstream parties are unable to ascertain the manufacturer's intent, they could be acting unlawfully without knowledge. Sumption and Reed advocated an outward presentation test, potentially founded on German decisions. The physical characteristics such as the product's leaflet are decisive.

It is notable that Sumption admits in his judgement that this test may give limited protection to the patentee. Consider a situation wherein the non-patented use is only 20% of the market and the patented use is 80% of the market. Using Sumption's test, if the generic manufacturer stated that the product should be used for the non-patented use, but was producing vastly in excess knowing the product would be going towards the patented use, they would be free from liability. Sumption commented on such extreme cases where the outward packaging is a charade but stated that this is a problem for the legislature to resolve rather than the courts.

The outward presentation test was rejected by Lords Briggs and Hobbs on the basis that it offers inadequate protection to the patentee. They advocated a test of subjective intention as evidenced by the context and facts. Details such as the packaging and leaflets, as well as internal documentation, will be considered in order to ascertain the intent of the company.

Lord Mance rejected the subjective intention test and was clearly uncomfortable with the possible impact of the outward presentation test as the sole test. He offered an opinion on what might infringe, such as not using a 'skinny label', and stated that in some extreme cases the patentee must go further and positively exclude the patented use (although there is an ongoing debate in regulatory law whether this is permissible). It was suggested that Lord Mance's approach may not be materially different in practice from the subjective intention test.

There are several lessons to be gleaned from this in-depth discussion. Firstly, that foreseeability is not the test. Additionally, although 'skinny labels' in many cases will absolve liability, under both tests, sometimes the facts may justify liability and disclosure will be highly relevant; particularly, to the subjective intention test. This case related to Swiss-type claims but it was opined that the approach is unlikely to be different for EPC 2000 claims. Although this is different law, the same policy matters will be considered.

The court must be wary of undermining the development of second medical uses for drugs. If the industry does not have effective patent protection, this could have an effect on whether, and in what order, the industry develops new uses for drugs. Perhaps the solution lies outside of patent law, in the reconsidering of our prescribing and dispensing practices.