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Pregabalin – The Ruling of the UK Supreme Court

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Today, after nine months of waiting, the decision of the UK Supreme Court in the pregabalin litigation was handed down. Like Brexit and the nation, it is clear that the Supreme Court Judges were divided on several crucial issues.

In this post, we will not attempt to give a detailed analysis of the decision but rather to give a short summary of the principal points. A more detailed analysis will follow in the coming days.

The background to the case is well known. Warner-Lambert had a patent with Swiss-type claims to the use of pregabalin in the treatment of pain (the "Patent"). The Patent had subsidiary claims to the use of pregabalin in inflammatory pain and neuropathic pain. Following the expiry of the compound patent for pregabalin in spring 2013, various generics companies wanted to sell pregabalin for non-patented indications including epilepsy and general anxiety disorder. However, the law was unclear as to what additional steps the generics companies should take, besides carving out pain from their label, to try and ensure that their pregabalin medicines were not used for the treatment of pain whilst Warner-Lambert's patent was in force. In addition to taking such steps, the generics companies also sought to revoke the Patent and thus clear the way ahead of sales of their medicines for the treatment of pain. Warner-Lambert denied that the Patent was invalid and alleged that the Patent was infringed.

At first instance, Arnold J. had held that the main claims of the Patent were invalid for lack of sufficiency and that in any event, they were not infringed. A post-trial application to amend the Patent to peripheral neuropathic pain was not permitted as it was held to be an abuse of process.

In the Court of Appeal, Arnold J.'s findings on validity were substantively upheld. However, the Court considered that the correct approach to the issue of infringement was that an objective intention test should be applied, and that a generic could in principle be liable for infringement if it could reasonably foresee that some of its product could be used for the patented purpose. However, the Court of Appeal held that a generic could escape liability if it had taken "all reasonable steps" to ensure that its medicine was not intentionally administered for the patented indication.

Today's ruling considered four issues: (i) construction of the claims, (ii) abuse of process, (iii) sufficiency of disclosure and in particular the question of plausibility and (iv) (*obiter*) the correct test for infringement of Swiss-type claims to the use of drugs in medical indications.

Construction

Lord Briggs (with Lords Reed, Sumption and Hodge agreeing) followed both Arnold J. and the Court of Appeal in holding that "*neuropathic pain*" means all neuropathic pain, and not only peripheral neuropathic pain. Lord Briggs explained that validating construction, the idea that, where possible, a construction should be preferred which results in the relevant claim being valid, does "*not usually have a significant place in modern patent law*" and "*would cut across the legal policies underlying patent protection*". He also noted that, for second medical use claims, there is a particular need for legal certainty and that issues of construction should be addressed, as far as possible, by deciding "*what it really does mean*". It seems that Lord Mance was not quite as confident about this construction as the other Lordships. However, ultimately he also agreed.

Abuse of Process

The Lordships unanimously agreed with the Court of Appeal and Arnold J. that post-trial amendments resulting in a new claim that had not been adjudicated on at trial were not allowed. Lord Sumption stated that the submission made by Warner-Lambert came "*nowhere near surmounting those steep hurdles*" for the Supreme Court to interfere in procedural points. In any event, as will become clear in the following paragraph, contrary to the findings of the lower courts, the Supreme Court held that the proposed amendments would not have saved the Patent.

Sufficiency

The issue of plausibility also saw their Lordships split in opinion. The majority favoured the decision of Lord Sumption (Lords Reed and Briggs concurring on this issue), who concluded that the issue of plausibility is just an aspect of the underlying principle of sufficiency: that a patent monopoly must be justified by the technical contribution to the art. The principle was that: "*the specification must disclose some reason for supposing that the implied assertion of efficacy in the claim is true*" and, whilst the common general knowledge may be useful in interpreting the teaching of a patent, there must be a disclosure in the patent to which the common general knowledge is applied. This disclosure cannot be merely that something is worth trying. However, for second medical use claims the disclosure may, for example, amount to reasonable scientific grounds for the skilled person to expect there were reasonable prospects of the invention working based on "*a direct effect on a metabolic mechanism specifically involved in the disease*". The test is "*relatively undemanding*" and is applied to a "*modest standard*" at the effective date of the patent.

Lords Hodge and Mance dissented, stating their view that the EPO authorities were clear that the standard of proof required for plausibility was lower and satisfied if there was a claim which "*appears scientifically possible, even though it cannot be said to be even prima facie established, without for example testing or assays*". Their Lordships thought that "*only if the person skilled in the art would have significant doubts about the workability of the invention*" from the disclosure in the patent would the patent be then implausible.

Infringement

While the Lordships' comments on this issue are *obiter*, they make for an interesting read.

In relation to indirect infringement, quite simply, the Supreme Court unanimously agreed that prescribing, dispensing or using generic pregabalin to treat the patented indication does not put the invention into effect, nor does it supply means essential to put the invention into effect. This is because, as explained by Arnold J. at first instance, Swiss-type claims protect the manufacture of

pregabalin for the designated use and not the subsequent use of pregabalin in treating the patients.

The position on direct infringement is much more complex, with a 2:2:1 split in opinion. Lords Sumption and Reed favoured the "*outward presentation*" test, in which the intention of the infringer is irrelevant and the sole criteria for determining infringement is how the product is presented post-manufacture (i.e., what is expressly stated on the SmPC and patient information leaflet). In reaching that conclusion, the Lordships suggested that an infringement test based on intention would be "*contrary to principle and productive of arbitrary and absurd results*". While acknowledging that the outward presentation test is not perfect, they nevertheless considered it to be "*less imperfect than any other*". Their Lordship's appeared to recognise that the proposed test does not address a possible "charade" by a generics company, e.g. labelling its product for one use and actively marketing it for another. However, the patentees' interest is not the only consideration and this imperfection arose as a direct result of the limitations inherent in Swiss-type claims. It was recognised that "*outward presentation*" was a rough paraphrase of "*sinnfällige Herrichtung*" or "*manifest preparation*" which was, until recently, the touchstone of the German courts for the infringement of Swiss-type claims.

Lord Mance proposed a softer version of the outward presentation test, noting that, in rare cases, context may make it obvious that the patient information leaflet and SmPC are not to be taken at face value, and that there may be circumstances where the generic company must positively exclude certain uses. He did not, however, provide any further guidance on what circumstances or context might be relevant. The Judge mentioned the idea of a notice positively excluding the patent-protected use which, according to the authors' understanding, is not easily done under established principles of regulatory law.

Finally, Lords Hodge and Briggs "*not without some reluctance*" disagreed with the outward presentation test. They instead favoured a "'so-called' subjective test", largely supporting Arnold J.'s first instance decision. They suggested that whether dealings in the product after manufacture give rise to infringement depends entirely on whether the product was "tainted" during manufacture. They suggested that a mental element in the mind of the manufacturer must form part of a Swiss-type claim (and not s60(1)(c) Patents Act 1977), when the "*for*" is properly construed. They noted that while the way that the product is presented to the market will "*often, or indeed usually*" provide evidence of the manufacturer's intended purposes, the subjective intent may be proved "*objectively by words, conduct or even inactivity*", and the Court could rely on "*anything from which the court could properly find that the manufacturer had such a purpose could be relied upon, including targeted disclosure, during litigation, of documentary records of the manufacturer's decision-making process*".

This is a major decision with important ramifications for all stakeholders in the life sciences industry. At first glance, it is perhaps disappointing that the Supreme Court has not chosen to follow the direction of travel in Europe, which is broadly consistent with the approach of the Court of Appeal requiring the generics to take reasonable steps to avoid use of their medicines for the patented indication. However, the fact that the opinion on infringement are: (i) *obiter*; (ii) specifically restricted to Swiss-type claims; and (iii) leave the door ajar in some respects suggests that this may not be final word on the issue even though it is the end of the road for this case.

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