

THE HIGH COURT CONSIDERS THE DOCTRINE OF EQUIVALENTS IN THE CONTEXT OF PATENT INFRINGEMENT AND NOVELTY

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Legal Briefings – By **Sebastian Moore, Andrew Wells and Julie Chiu**

The High Court in [Generics \(U.K.\) v Yeda Research](#) has considered the correct approach to the interpretation of patent claims in light of the recent Supreme Court decision in *Actavis v Eli Lilly*.

This High Court decision provides early indication of some possible ramifications of the decision in *Actavis* in relation to the assessment of novelty, but considerable uncertainty remains. What is clear is that *Actavis* represents a significant change in English patent law.

The judge also reinforced that common general knowledge will only comprise information which is proven to have been common general knowledge in the UK at the relevant date, and refused to grant an Arrow declaration on the facts of this case.

BACKGROUND

Generics (U.K.) Limited t/a Mylan and Synthon BV (“**Claimants**”) sought revocation of EP 2 949 335 in the name of Yeda Research and Development Company Limited, of which Teva Pharmaceutical Industries Limited is exclusive licensee (together, “**Defendants**”). The patent claims a dosing regimen for the treatment of multiple sclerosis by subcutaneous injection of 40 mg of glatiramer acetate (“**GA**”) every seven days with at least one day between each injection. Teva markets GA for the treatment of multiple sclerosis under the brand name, Copaxone.

It was accepted that the Claimants infringed the patent if validity was upheld.

COMMON GENERAL KNOWLEDGE (“CGK”)

Arnold J clarified that common general knowledge must be shown to be CGK in the UK and not elsewhere in the world. However, depending on the therapeutic area in question, and on the facts of the case in question, CGK in other jurisdictions (such as the USA in this case), might be taken to be CGK worldwide, including in the UK.

CONSTRUCTION OF PATENT CLAIMS

Arnold J noted the change in the law regarding claim interpretation in relation to infringement following the Supreme Court’s decision in *Actavis UK Ltd v Eli Lilly and Co* [2017] UKSC 48, which we reported [here](#). As foreshadowed in our report, a key question is whether *Actavis* had changed the correct approach to claim construction (aside from the issue of how equivalents are to be treated), which was relevant in this case in relation to novelty. The Defendants argued that the law post-*Actavis* required patent claims to be interpreted literally, in the same way that commercial contracts are construed. In contrast, the Claimants argued that the law on this issue had not changed, and that a purposive construction should be adopted. Arnold J held that patents differ from commercial contracts in key respects, such that the context of a patent (including the purpose for which it was drafted how the skilled person would read it) needs to be taken into account when interpreting it.

NOVELTY

Arnold J then considered whether *Actavis* had changed the correct approach to be adopted by the court in assessing novelty. The judge noted that this issue was not considered by in the Supreme Court’s judgment and, in his view, a definitive position could only be laid down by the Supreme Court in a further decision.

When assessing whether a piece of prior art disclosed subject-matter which, if performed, would infringe the attacked patent, the central question was whether the doctrine of equivalents should be applied to determine the scope of the claims.

After considering the previous case law, the EPO Boards of Appeal jurisprudence and the legal basis of the Supreme Court’s decision in *Actavis*, Arnold J concluded that a claim would only lack novelty if the prior publication disclosed subject matter which fell within the claim on its proper interpretation i.e. without applying the doctrine of equivalents to the claim. In practical terms, as the judge noted, this leads to a divergence in the approach which previously applied to assessment of infringement in the same way as it applied to assessment of novelty. As the Claimants submitted, this may result in a situation in which a claim could be infringed by a person who performed what is taught by a prior publication, yet that prior publication would not be sufficient to destroy the novelty of the patent.

On the basis that the skilled person would regard a 40 mg QOD regimen, which was disclosed in a prior art patent, to be distinct from the 40 mg TIW regimen claimed in the patent, Arnold J found that the patent was novel over the prior art (but as discussed below, ultimately revoked the patent due to lack of inventive step).

Although it is clear from the judgment that novelty cannot be destroyed under the doctrine of equivalents, Arnold J nevertheless went on to consider the outcome if the doctrine of equivalents did apply to deprive claims of novelty. The skilled person would think there was no difference in efficacy between a 40 mg QOD regimen and a 40 mg TIW regimen. Therefore, the claims would, if the doctrine of equivalents applied to novelty, lack novelty over the prior art patent.

INVENTIVE STEP

Based on the reasoning above, Arnold J held that the patent was obvious in light of the prior art patent disclosing the 40 mg QOD regimen, which meant that the claimed 40 mg TIW regimen was obvious to try with a fair expectation of success.

In case he was wrong on the finding of obviousness, Arnold J also considered arguments relating to lack of technical contribution and, in particular, an alleged squeeze between obviousness and plausibility.

ARROW DECLARATION

The Claimants sought an Arrow declaration that the use of the Claimants' product would have lacked novelty and/or been obvious as at the priority date with regard to the dosing regimen. After considering recent case law, Arnold J refused to grant an Arrow declaration for several reasons, including his finding that the Defendants had not sought to shield the subject matter from scrutiny by the courts (the patentee having vigorously defended the validity of the patent in issue) and that no additional useful purpose would be served by such declaration in light of his reasoned judgment on invalidity.

KEY CONTACTS

If you have any questions, or would like to know how this might affect your business, phone, or email these key contacts.



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