UK Supreme Court decision alters UK approach to infringement by equivalents

This decision on Eli Lilly's Alimta patent reverses lower Courts' rulings and finds claims limited to "disodium" to be directly infringed by other salts and free acid.

Lilly's European patent is directed to a dosage regimen involving co-administration of the anti-cancer drug pemetrexed (marketed as Alimta) with vitamin B12. The claims specifically recite "pemetrexed disodium", whereas Actavis' proposed generic versions of the product included the free acid or different salts (pemetrexed diacid, ditromethamine and dipotassium).

This dispute started back in 2012 when Actavis sought a declaration for non-infringement in the UK and other jurisdictions including France, Italy and Spain. There have been multiple procedural twists and turns, but the headline from the earlier decisions is that there had been findings of non-infringement wherein salts other than disodium did not directly infringe the patent, but findings of indirect or contributory infringement, partly because Actavis' products would form the disodium product when reconstituted in saline, due to the abundance of sodium ions.

The Supreme Court decision focuses on direct infringement.

New test for infringement by equivalents

Unlike the US and several other European jurisdictions, the UK courts have historically not adopted a "doctrine of equivalents". The present decision emphasises the importance of assessing scope of protection in two stages: (i) considering infringement under **normal interpretation**; and (ii) infringement by **immaterial variation**. It is accepted in this case that under "normal interpretation" the proposed Actavis products do not infringe.

The decision resets the questions used to determine whether a variation is 'immaterial' in the following terms:

i) Notwithstanding that it is not within the literal meaning of the relevant claim(s) of the patent, does the variant achieve substantially the same result in substantially the same way as the invention, i.e. the inventive concept revealed by the patent? If yes:

ii) Would it be obvious to the person skilled in the art, reading the patent at the priority date, but knowing that the variant achieves substantially the same result as the invention, that it does so in substantially the same way as the invention? If yes:

iii) Would such a reader of the patent have concluded that the patentee nonetheless intended that strict compliance with the literal meaning of the relevant claim(s) of the patent was an essential requirement of the invention?

To find infringement, the answer to this final question must be no.

The wording of this new test should make it easier for a patentee to establish infringement outside the literal wording of the claims. For instance, the second question now allows the skilled person post-priority knowledge that the variant works, whereas the old approach required this to have been obvious at the priority date.

The third question does allow specific claim language to bite, but the Supreme Court's commentary emphasises that it is only an escape for infringement in certain circumstances.

The new approach brings the UK more closely into line with other European courts (particularly Germany, Italy, and the Netherlands).

In the present case, the court found Actavis' proposed products to satisfy the newly adopted test and therefore to infringe, with the following technical rationale:

(i) Actavis' compounds worked in substantially the same way as pemetrexed sodium, e.g. because they provided the pemetrexed anion;

(ii) knowing that Actavis' compounds worked, it would have been obvious that they do so by providing the pemetrexed anion; and

(iii) while the language of the claim was clearly limited to disodium, it was not clear that the patentee intended to cover only disodium salts; for instance, the description suggested the invention would work with any anti-folate compound.

This decision on infringement was also found to apply in France, Italy, and Spain.

File wrapper estoppel

The decision also looked at the relevance of prosecution history when assessing scope of protection.

Looking at the file contents has typically been discouraged by the UK courts (with one previous decision saying "life is too short"). The Supreme Court suggested a "**sceptical, but not absolutist attitude**" and set out the two situations where it would be appropriate: (i) if the point at issue is unclear based on the specification, and the file unambiguously resolves the point, or (ii) if it would be contrary to the public interest to ignore the file, e.g. where a patentee has stated previously that it would not enforce the patent against a particular variant.

In this case, the Supreme Court found that the contents of the file did not justify departure from the above conclusion on infringement. For instance, the limitation from any anti-folate compound down to pemetrexed disodium was made to address formal objections against the broader scope (and the Supreme Court suggested even these objections might have been wrong). Indeed, the patentee had attempted to claim "pemetrexed", but the examiner insisted that "disodium" be included for compliance with added matter rules (Article 123(2) EPC). The Supreme Court suggested that this might have been different if the amendment had been made to address prior art.

Summary

The new approach will make it more likely that immaterial variants will fall within the scope of protection and will be binding on the lower Courts. However it remains to be seen how it will be interpreted with different facts.

Authors: Richard Newell, Martin Crow & Camilla Balleny

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For more information, please contact: email@carpmaels.com.

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