

The UK Supreme Court re-vitalises patent infringement by equivalents

The question of whether something that falls outside the literal wording of a patent claim is nevertheless an infringement, is one that the courts have had to consider on numerous occasions. Now, in the case of *Eli Lilly v Actavis*, the UK's highest Court, the Supreme Court, has decided that account should be taken of whether an alleged infringement is an equivalent of the claimed invention. Compared with practice over the last decade, this is a shift towards broadening the protection that a Patentee enjoys.



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History of the litigation

Eli Lilly's ALIMTA product has been on the market since 2004 and it is used to treat non-small cell lung cancer and pleural mesothelioma. ALIMTA comprises the chemotherapy drug pemetrexed together with vitamin B12. Pemetrexed had been known for some time when Eli Lilly developed the product, but the breakthrough came with the discovery that damaging side-effects could be largely avoided by co-administering it with vitamin B12. Eli Lilly obtained a patent for that invention.

In this litigation, Actavis was attempting to clear the way for launch of a generic ALIMTA product by obtaining a declaration that its product did not infringe Eli Lilly's patent.

Actavis was proposing to market pemetrexed in the form of its dipotassium salt. Importantly, Eli Lilly's patent recites in its claim 1 "pemetrexed disodium". Actavis succeeded at first instance and at the Court of Appeal level in persuading the Court that its pemetrexed dipotassium product fell outside the claims as they required pemetrexed disodium. It was common ground that the dipotassium salt of pemetrexed worked in the same way as the disodium salt.

Equivalents

Both the first instance and Court of Appeal judgements considered the case law on the treatment of equivalents in the UK. The previous cases before the UK's highest court (*Catnic*, *Improver* and *Kirin-Amgen*) had put the primary emphasis on the interpretation of the claim, essentially asking: what does the claim mean to the skilled person, and then is that claim infringed?

The Supreme Court has now held that that analysis does not give sufficient weight to equivalents. Instead, it should first be considered whether the variant infringes the claim as a matter of normal interpretation of the claim. If not, then it must be investigated whether the variant nonetheless infringes because it varies from the invention in a way or ways which is or are immaterial. The most recent case law had conflated these two issues.

How to assess equivalents:

The UK Patents Courts prefer not to set out concrete tests to substitute for an essential question – here "is there infringement?". However, the Supreme Court judgement includes a sequence of three questions that can serve as guidelines for assessing equivalents. The Court expressed its new questions as follows:

- (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?

(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?

(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?

In order to establish infringement in a case where there is no literal infringement, the patentee needs to establish that the first two answers are 'Yes' and the third answer is 'No'.

On the facts of the case, the Court found that: pemetrexed dipotassium achieves substantially the same result in substantially the same way as pemetrexed dipotassium; it would have been obvious to the person skilled in the art that that is the case; and such a reader of the patent would not have concluded that the patentee nonetheless intended that strict compliance with the literal meaning of pemetrexed disodium was an essential requirement of the invention. Accordingly, Actavis's product infringed the Eli Lilly patent.

Prosecution file history

The Supreme Court also had to consider the weight that should be given to any actions or comments that the patentee made during the examination of the patent application. Most courts in Europe have been reluctant to give the prosecution file prominence when interpreting the claims of a patent. The Supreme Court endorsed this approach, whilst steering clear of an absolute bar to looking at the prosecution history. The Court said that reference to the file is only appropriate where:

(i) the point at issue is truly unclear if one confines oneself to the specification and claims of the patent, and the contents of the file unambiguously resolve the point, or

(ii) it would be contrary to the public interest for the contents of the file to be ignored - this might, for example, be where the patentee had made it clear to the EPO that he was not seeking to contend that his patent, if granted, would extend its scope to the sort of variant which he now claims infringes.

Effects:

The full effects of this Decision will only be known when the lower courts implement it in their decisions in the coming years. However, patentees should be able to take heart that potential infringers should not be able to avoid patent infringement only by making immaterial changes to a product. It remains that case, however, that a patentee will sleep easier, and avoid potentially expensive litigation, if

he continues to draft his patent applications and take them forward to grant in a form that clearly catches as many potential infringements as possible without having to rely on a court's willingness to extend a patent's scope to include equivalents.

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