

UK Supreme Court Breathes New Life to the Doctrine of Equivalents

by Ron Moscona

In what is perhaps the most important development in English law of the last decade in this area of interpretation of patent claims and patent infringement, the UK Supreme Court gave new life to the doctrine of equivalents in its decision in ***Actavis v. Ely Lilly*** [2017] UKSC 48.

The relevant legislation, the Protocol on the Interpretation of Art. 69 of the European Patent Convention, as amended in 2000, sets out general rules on the interpretation of the rule of infringement under the EPC (which applies to European Patents as well as domestic UK patents). Art. 1 of the protocol provides, in essence, that claims should be read against the context of the description and the drawings (avoiding strict literal interpretation but noting that the claim as drafted is not merely a guideline). Art. 2 states that *“For the purpose of determining the extent of protection conferred by a European patent, due account shall be taken of any element which is equivalent to an element specified in the claims.”*

Both before and after the 2000 amendment of the Protocol (which introduced Art. 2) the UK court adopted a cautious approach that preferred to view the issue of equivalents as part of the “purposeful interpretation” of patent claims and not as a separate issue. Whilst the approach clearly rejects a strict literary approach to claims interpretation, by viewing the issue of equivalents as a matter of interpretation, courts tended to avoid departing too much from the language of the claim.

The UK courts developed a three step test (known as the *Improver* questions after the well-known case *Improver Corp v Remington Consumer Products* of 1990 concerning a patent for the Epilady product) to assist in analyzing the question whether a variant to an integer required under the patent claim takes it outside the protection of the patent. The courts would ask:

- Whether the variant has a material effect on the way the invention works?
- If no, would that be obvious to the person skilled in the art (the addressee of the

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patent), and

- Whether that person would nevertheless have understood from the language of the claim that the patentee intended that strict compliance with the primary meaning of that integer was an essential requirement of the invention.

The main change of approach introduced by the Supreme Court in **Actavis**, which according to the Court would align the position in the UK more closely with the way the Protocol is interpreted by the German and Dutch patent courts, concerns the main premise that a direct infringement can occur even if on a proper interpretation of the claim there is no infringement, provided the variance is immaterial. The Court adopted the same steps set out in the *Improver* case but with modifications. The Court observed that the second step can be too strict and that it did not need to be obvious to the person skilled in the art at the priority date of the patent that the variant would work in the same way as the integer referred to in the claim. It is sufficient that it would be obvious that the variant achieves the same result (or works in the same way), given the knowledge that it actually works.

The distinction was relevant to the case at hand where the invention concerned the combination of a particular compound (pemetrexed) used for cancer treatment, with vitamin B12, to avoid toxicity. The patent claims referred to a particular salt variant of the compound – pemetrexed disodium. That variant was an existing Ely Lilly cancer treatment (sold under the brand name ALIMTA) which the company used in testing the patented compound. The defendant, Actavis, replaced pemetrexed disodium with pemetrexed diacid (the free acid form of pemetrexed), and with the alternative salt forms, pemetrexed ditromethamine and pemetrexed dipotassium.

It was clear that these compounds were outside the literary meaning of the patent claims that referred specifically to “pemetrexed disodium”. The lower courts, applying the *Improver* questions concluded that it would not have been obvious to the person skilled in the art that these alternative compounds would work in the same way as pemetrexed disodium because the compounds would need to be tested before that conclusion could be reached. However, the Supreme Court observed (based on the evidence) that it would have been a routine exercise to test these alternative forms of pemetrexed and that (given the known art at the priority date) it would have been obvious to the person skilled in the art that the use of these alternatives would achieve the same result (when combined with vitamin B12), or work in the same way, if indeed they worked.

The Court pointed out that in principle it may be obvious to the notional addressee of the patent that the variant achieves the same purpose or works in the same way as the original integer, even if that variant is based on developments that occurred after the priority date of the patent and even if that development represented an inventive step. In other words, a variance which itself might be patentable might not necessarily avoid the infringement, if assuming knowledge that the variant works, it would be obvious to the person skilled in the art that it works in the same way as the original integer (although in many cases such a variance would not be deemed immaterial in other respects).

The Court answered the third *Improver* question in the negative (the person skilled in the

art would not read the reference to pemetrexed disodium in the patent as a strict requirement that precludes other forms of pemetrexed). It was noted in that context that the description of the invention in the patent did not refer specifically to pemetrexed disodium but rather to the family of compounds known as “antifolates”. On that basis, it found a direct infringement of the patent.

The Court in the **Actavis** case also took into consideration the prosecution history of the patent. The Court confirmed in its decision the sceptical approach taken by English law towards reliance on the prosecution file as an aid to interpretation, without however precluding it altogether. The file in the case at hand showed that the patentee tried in fact to amend the claims to refer to “pemetrexed” in general, but the examiner rejected the amendment on the grounds that it introduces ‘added subject-matter’. The examiner subsequently allowed a reference to be made to “pemetrexed disodium” instead. This was allowed because it was the variant of the compound used in the experiments conducted by the patentee. The Supreme Court found that this history did not preclude treating other forms of pemetrexed as equivalents.”

The decision in **Actavis** is set to pave the way to heavier reliance on equivalents in patent infringement claims in the UK, particularly in relation to chemistry and pharmaceutical patents and is likely to raise the barrier to competitors seeking to develop compounds and other products around the language of patent claims. While the change of approach heralded in this case is clearly applicable to the analysis of chemistry patents, where it is not unusual for several similar compounds to be interchangeable for producing the same result or purpose, the decision is not limited to that field and may well have an impact in other patent areas.

The language of the patent claim will remain the starting point for any infringement analysis and the next step would necessarily be to examine the description and the drawings to provide the contextual basis for a purposeful interpretation of the language. But the **Actavis** case offers a new line of attack for patentees (and a separate source for concern for potential defendants) that the replacement of an integer with a close alternative, even if it clearly takes the defendant’s product outside the scope of the patent claims as drafted, may not necessarily be the end of the infringement analysis. If the replacement is deemed immaterial, there is still a chance that an infringement would might yet be found.