The Doctrine Of Equivalents reaches the UK

Introduction

The British Supreme Court in *Eli Lilly and Company (Appellant) v Actavis UK Limited and others (Respondents)* [2017] UKSC 48 has introduced a doctrine of equivalents into UK law. This decision profoundly changes the way issues of infringement will be considered in the future by the UK Courts. In order to understand the effect of this change, it is first helpful to recap the existing statutes and their previous interpretation by the UK Courts. Against this background, the decisions of the Patents Court and the Court of Appeal leading up to this Supreme Court decision will be considered before the Supreme Court decision itself is analysed.

Statutory Provisions

As a member of the EPC, the UK approach to determining the scope of protection must adhere to Article 69 EPC and the Protocol for its interpretation. These provisions apply to all of the EPC Contracting States but their interpretation and implementation varies country by country.

According to Article 69 EPC, the scope of protection of a patent is determined by its claims. The description and any drawings may, however, be used to interpret the claims. Article 1 of the Protocol associated with Article 69 requires that this scope should provide a fair protection for the Patentee, with a reasonable degree of legal certainty for third parties. According to Article 1, the claims must neither be interpreted in a strict literal sense, nor on the other hand be used as a mere guideline to the scope of protection as derived from the specification as a whole.

Whilst Article 1 of the Protocol provides guidance as to how the claims should not be interpreted, it is left to the Courts of the Contracting States how they should go about balancing the interests of the Patentee with those of third parties.

Article 2 of the Protocol requires that the Courts should take into account any element which is equivalent to an element specified in the claims when determining the scope of protection. It fails however to explain how equivalent elements should be taken into account. The Supreme Court has decided that it requires a doctrine of equivalents to be adopted.

Previous UK approach to scope of protection

In order to appreciate the significance of this decision, it is first worth briefly summarizing the previous approach of the UK Courts to how the scope of protection should be determined. *Catnic Components Ltd v Hill & Smith Ltd* [1982] RPC 183 provided the foundation for this previous approach. The patent in this case was granted under pre-EPC legislation, but the decision was subsequently held to be consistent with Article 69 EPC and its associated Protocol.
The *Catnic* case related to a component of a box lintel which, according to the claims, included a ‘vertical’ component. This component in the alleged infringing product was angled at 6° from the vertical.

A strict literal interpretation of the claims would have led to a finding of non-infringement. However, the Court adopted what they termed as a ‘purposive construction’ of the claim language which meant interpreting the claims from the perspective of the skilled person to whom the specification was addressed; in this case a tradesman operating in the building trade. Such a person would understand that ‘vertical’ merely meant ‘vertical enough to work’, such that a mathematically precise interpretation of this term was inappropriate. This resulted in the Court reaching a finding of infringement.

The same approach was adopted in *Improver Corp v Remington Consumer Products Ltd* [1990] FSR 181, but with a different outcome. The patent in issue was directed to an epilator with a curved helical spring having gaps between its coils which opened and closed upon rotation of the spring in order to pluck body hairs. The alleged infringing device operated on the same principle, but had a rubber rod with slits in place of the helical spring.

The Court used a structured approach, heavily influenced by *Catnic*, to assess whether this variant, i.e. the rubber rod with slits, was encompassed by the term helical spring and thus constituted an infringement. This approach involved asking the following questions which became known as the *Improver* questions:

1) Does the variant have a material effect upon the way the invention works? If yes, the variant is outside the claim. If no-

2) Would this (i.e. that the variant had no material effect) have been obvious at the date of publication of the patent to a reader skilled in the art? If no, the variant is outside the claim. If yes-

3) Would the reader skilled in the art nevertheless have understood from the language of the claim that the Patentee intended that strict compliance with the primary meaning was an essential requirement of the invention? If yes, the variant is outside the claim.

Applying these questions to the underlying facts, questions 1) and 2) were respectively answered in the negative and affirmative. This meant that the question of infringement hinged on the issue of whether or not the skilled person would have considered that the Patentee intended strict compliance with the primary meaning of the term ‘helical spring’. The Court held that the skilled person would consider ‘helical spring’ to mean exactly that, i.e. 3) was answered in the affirmative. The meaning of this term did not extend in a figurative sense to a rubber rod with slits leading to a finding of no infringement.

It is important to note that this previous UK approach did not permit the scope of protection to escape from the language of the claims. This position was confirmed in *Kirin-Amgen Inc v Hoechst Marion Roussel Ltd* [2004] UKHL 46 in which the alternative approach involving a literal construction with extension of protection (outside the language of the claim) to ‘equivalents’, as per the US doctrine of equivalents, was explicitly criticised. The House of
Lords, which was re-named the Supreme Court in 2009, considered that Article 69 EPC did not mean that an equivalent falling outside the purposive construction of a claim could nevertheless be encompassed. Rather, they held that knowledge of equivalent features was part of the background knowledge of the skilled person, and thus would necessarily inform interpretation of the claim language. Purposive construction was thus held to be in conformity with Article 2 of the Protocol.

**Pemetrexed – Patents Court (Actavis v Eli Lilly [2014] EWHC 1511 (Pat))**

It was in this context that Eli Lilly brought an infringement claim against Actavis in the UK Patents Court (part of the High Court). The patent in suit related to a combination therapy of pemetrexed and vitamin B12 for the treatment of cancer. Pemetrexed is a potent anti-cancer agent but has the drawback of high toxicity. It was discovered by Eli Lilly that vitamin B12 reduced the toxicity of pemetrexed to allow its anti-cancer activity to be exploited.

The originally filed claim was directed to a method of administering an antifolate (of which pemetrexed is an example) in combination with a methylmalonic acid lowering agent. However, it became necessary during prosecution of the European application to narrow this scope. The Patentee attempted to amend claim 1 (in Swiss form) as follows: Use of pemetrexed in the manufacture of a medicament for use in combination therapy for inhibiting tumor growth in mammals wherein said medicament is to be administered in combination with vitamin B12 or a pharmaceutical derivative thereof.

The application as filed did not, however, disclose ‘pemetrexed’ as such. This compound was only disclosed in the form of its disodium salt. In order to overcome an objection of added subject-matter, Eli Lilly was forced to limit claim 1 during prosecution to the use of pemetrexed disodium.

The Actavis product capitalised on Eli Lilly’s discovery of the combination of pemetrexed and vitamin B12, but used either the free acid form of pemetrexed or alternative salts, such as pemetrexed dipotassium. The Patents Court held that the Actavis product did not infringe.

The Court considered the issue with reference to the Improver questions and, in relation to the second question, held that it would not be obvious to the skilled team that pemetrexed in the free acid form or the dipotassium salt would have no material effect on the way the invention works. The diacid or salt had to be sufficiently soluble for patient administration, such that the invention could be put into effect. Given that the solubilities of these compounds could not have been predicted by a skilled person, the Court answered the second Improver question in the negative.

Even in the event of an affirmative answer to the second Improver question, the Court considered in relation to the third question that the meaning of ‘disodium’ is unequivocal and that ignoring this limitation would not give proper effect to the Protocol as it would amount to treating the claims as a mere guideline.

It is noteworthy that, somewhat unusually in the UK, the prosecution file was considered by the Court when considering the issue of claim construction. The use of the prosecution history counted against Eli Lilly, in spite of their argument that the file provided evidence of...
their intention to extend protection to other forms of pemetrexed. The file revealed that Eli Lilly had deliberately limited the claim to pemetrexed disodium during prosecution to overcome an added subject-matter objection.

Whilst not being relevant to the main discussion concerning the scope of protection, it is noted for completeness that the Patents Court went on to find that Actavis did not indirectly infringe the patent either. Before its administration to a patient, the Actavis product would be dissolved in saline. In spite of pemetrexed anions and sodium cations being simultaneously supplied to the patient, the Patents Court considered that at no stage is pemetrexed disodium actually used in the manufacture of a medicament by anyone. This construction limits ‘pemetrexed disodium’ used in the claim to its solid salt form.

**Pemetrexed – Court of Appeal (Actavis v Eli Lilly [2015] EWCA Civ 555)**

The Court of Appeal upheld the Patent Court’s finding on direct infringement. It approved the lower court’s approach to answering the second and third Improver questions. A proper construction of the claim did not extend protection to pemetrexed diacid or pemetrexed salts other than the disodium salt.

The Court of Appeal criticized the use of the prosecution file by the lower Court to aid construction. It held that the claims could be readily construed from the patent alone so that there was no need to consider the prosecution history.

Nevertheless, the Court of Appeal overturned the Patent Court’s decision regarding indirect infringement. The skilled team (which would include a chemist) would recognise that the term ‘pemetrexed disodium’ was not confined to the solid salt (*supra*) but could also refer to solutions containing a combination of pemetrexed anions and sodium cations. Accordingly, pemetrexed disodium would be used in the process of making up the medicament, i.e. dissolving the Actavis product in saline, such that Actavis indirectly infringed the patent.

**Pemetrexed – Supreme Court (Actavis v Eli Lilly [2017] UKSC 48)**

The Supreme Court revisited *Catnic, Improver and Kirin-Amgen*, and considered that the previous UK approach incorrectly conflated the two issues of claim interpretation and consideration of variants. In the Improver case, a slotted rubber rod was not interpreted as falling within the meaning of ‘helical spring’. The Supreme Court considered that this was not the correct test. Rather, it should have been considered whether the slotted rubber rod corresponded to a variant of a helical spring which had no material effect on the manner in which the patented invention operated. This approach which focuses on the inventive concept, not the specific words used in the claims, had been adopted in related actions in the German, Italian and Dutch Courts which had found in favour of the Patentee in parallel litigation to the UK Improver case.

The Supreme Court proposed the following new two-step test for deciding infringement cases:

a) does the variant infringe any of the claims as a matter of normal interpretation; and, if not,
b) does the variant nonetheless infringe because it varies from the invention in a way or ways which is or are immaterial?

If the answer to either issue is “yes”, there is infringement; otherwise, there is not.

It is not entirely clear what ‘normal interpretation’ means in step (a). It seems probable that the Supreme Court had purposive construction in mind, but this remains to be seen. Step (b) is an entirely new question previously unknown in British practice.

The Supreme Court proposed a three-stage test, representing a modified version of the Improver test, for answering the question of step (b):

(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 where there is no infringement as a matter of normal interpretation, a Patentee would have to establish that the answer to the first two questions is “yes” and that the answer to the third question is “no”.

Consistent with the decisions of the Patents Court and the Court of Appeal, the Supreme Court held that the Actavis product did not infringe as a matter of normal interpretation of the term ‘pemetrexed disodium’ (step a). The assessment therefore progressed to consideration of immaterial variants (step b).

Regarding question (i), Actavis accepted that the free acid pemetrexed and dipotassium salts of pemetrexed worked in the same way as pemetrexed disodium.

As discussed above, both the Patents Court and the Court of Appeal held that it was not obvious that such alternative salts would have no material effect on the way the invention works (second Improver question). However, the Supreme Court decided in relation to question (ii) that the question should be asked on the assumption that the notional addressee knows that the variant works. Thus the enquiry made in question (ii) of this new approach to variants is significantly less onerous than the second Improver question from a patentee’s perspective.

The Supreme Court went on to consider that the skilled person, on reading the full specification, would conclude that the Patentee did not intend to exclude forms of
pemetrexed other than the disodium salt from the scope of protection. There was nothing in the specification which, for instance, taught the importance of using sodium counterions. The negative answer to question (iii) led to a finding of direct infringement by Actavis.

The question of the prosecution history was also considered by the Supreme Court. The Court was generally sceptical of reviewing the prosecution file but conceded that it may be appropriate in certain circumstances. The Court held that consideration of the prosecution file may be warranted where the point at issue truly cannot be resolved by study of the claims and description, and the contents of the file unambiguously resolve the point, or where it would be contrary to the public interest for the contents of the file to be ignored. An example of the latter would be where a Patentee had made it clear during prosecution that he did not regard a variant as falling within the scope of protection, but subsequently asserts that this variant infringes.

The Supreme Court held that the prosecution file did not alter its findings on direct infringement. For completeness, it is noted that the Supreme Court upheld the Court of Appeal’s decision on indirect infringement.

Conclusions and Outlook

The Supreme Court has fundamentally changed the way in which infringement is assessed by introducing a doctrine of equivalents into UK practice. This scope of protection afforded by a patent now extends beyond the language of the claims to include immaterial variants.

The assessment of whether or not a variant infringes because it varies from the invention in a way or ways which is or are immaterial involves a three-stage test which is a more Patentee-friendly version of the previous Improver questions. The assessment has to be carried out on a case-by-case basis. Of key importance is whether the claimed feature which is varied in the alleged infringing product has been described in the specification as being essential to the inventive concept. This must be borne in mind when drafting specifications.

There are as yet no examples of the application of the Eli Lilly approach by the lower UK Courts. These will no doubt follow in the next year or so. Freedom-to-operate advice and infringement opinions in the UK will be much less certain in the future as a result of these developments.

If you have any questions, or require advice, please do not hesitate to get in touch.

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