

Dawn of an English Doctrine of Equivalents: immaterial variants infringe

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The Supreme Court reinvents patent infringement

The Supreme Court's landmark judgment in *Actavis v Eli Lilly* [2017] UK SC 48 is a change of direction for the English law on patent infringement. In reaching its decision, the Supreme Court has rewritten the existing infringement test and longstanding 'Improver'/'Protocol' questions. In doing so, it has adopted a doctrine of equivalents into the English approach, focussed on "immaterial variants".

The decision marks a new approach suggesting greater reliance on the inventive concept underlying the patent than on the wording of the claim.

The new approach is likely to result in greater scope of protection for patentees, as it has done in this case. Those seeking to avoid infringement face higher risk from this broader scope. The immediate challenge for all those using the patent system is that the scope of patents and the boundaries for infringement will be less predictable until further cases clarify how the courts will apply it. Meanwhile it will be worth revisiting important infringement analyses since the risks or potential gains may have changed.

The decision also suggests that the prosecution history (patent office file) will be more relevant than it has been. This will probably only have an impact in rare cases. However, it will be important to keep a closer eye on the potential

impact of statements made during prosecution on later infringement arguments.

The new approach

The Supreme Court criticised both the existing 'purposive' approach to construction of patent claims (laid down in *Catnic Components Ltd v Hill & Smith* [1982] RPC 183) and the related 'Improver'/'Protocol' guidelines (as formulated by Lord Hoffman in *Improver v Remington* [1990] FSR 181), concluding that, among other things, the existing approach 'fails to accord "a fair protection for the patent proprietor" as required by article 1 of the [EPC] Protocol'.

To address these criticisms, the Supreme Court has done two things. Firstly, it has replaced the single question of purposive interpretation (i.e. "what would a person skilled in the art have understood the patentee to have used the language of the claim to mean?") with a two-stage test that draws a clear distinction between literal infringement (in limb 1) and infringement that takes account of equivalents (in limb 2):

1. Does the variant infringe any of the claim(s) as a matter of normal interpretation? If the answer is yes, there is infringement. If not:
2. Does the variant nonetheless infringe because it varies from the invention in a way that is *immaterial*?

Secondly, it has reformulated the *Improver* questions and has framed them as guidelines for

determining what it is that makes a variant ‘immaterial’, and therefore by definition an infringing equivalent, under the second limb of the new test (see Box below).

The new *Improver* Questions

The three reformulated questions are:

1. 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?
2. 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?
3. 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 establish infringement in a case where there is no literal infringement, a patentee must establish that the answers are “yes”, “yes” and “no”.

The two step infringement test

The Court concluded that there are two relevant issues and stressed the distinction between them:

- (i) *whether there is infringement as a matter of normal interpretation*

The Supreme Court noted that the normal principles of interpretation were affirmed this year in *Wood v Capita Insurance Services Ltd* [2017] 2 WLR 1095. The Court concluded that, on

that basis, “in no sensible way” could the variants as permitted in the Actavis products be said to fall within the claim.

The relevant principles in *Wood v Capita* are:

- *that the court must ascertain the objective meaning of the language but that was not a literal exercise (focussed solely on parsing the wording) but required consideration of the contract as a whole and the factual background known to the parties at or before the date of the contract to give more or less weight to different elements.*
- *where there are rival meanings the court can take into account the implications of the rival constructions and reach a view on which is more consistent with business common sense.* This involves taking into account issues such as the quality of the drafting, the fact that it was a negotiated compromise and it may not have been possible to agree more precise terms.
- *Textualism and contextualism can be used as tools to assist in identifying the objective meaning but their value will vary according to the circumstances, i.e. in some cases textual analysis will be enough, in others there will need to be greater weight given to the factual matrix.*

It is not straightforward to apply the *Wood v Capita* principles to interpretation of a patent as it is a document put forward by the patentee identifying and claiming his invention, rather than a contract negotiated between two parties.

The Supreme Court in *Actavis* did confirm that a patent is to be “considered through the eyes of a notional addressee” of the patent (and this applies to both “normal interpretation and infringement by immaterial variants”). This seems consistent with the first principle of *Wood v Capita*.

In the first High Court case to consider the *Actavis* Supreme Court decision (*Generics & Ors v*

Yeda & Ors [2017] EWWC 2629 Pat)), Justice Arnold concluded that a patent was still to be given a “purposive” construction rather than a literal one. This is at odds with the Supreme Court’s approach, though possibly only in terminology. Arnold J goes on to conclude that the patent must be interpreted by interpreting the words and the claims in context and the context includes “the very purpose for which the document exists, namely to describe an invention.

The second principle does not seem to apply in patent cases: while there will be rival meanings and the court should take into account the implications of them, the choice is not based on which is more consistent with “business common sense”. The third factor seems to be inapplicable - a patentee surely should be taken to have chosen his words carefully and there is no context of negotiation.

(ii) *Does the variant vary from the invention in an immaterial way?*

Crucially this is now **not** a question of interpretation but a question of to what extent the scope of protection of the patent should extend beyond the claims.

The Supreme Court notes that this approach complies with the requirements of Article 2 of the Protocol on interpretation of Article 69 to the European Patent Convention (see Box 2) because it:

- (i) squarely raises the issues of equivalents (while limiting it to immaterial variants) and
- (ii) involves balancing the competing interests of the patentee (fair scope of protection) and of clarity (a reasonable degree of legal certainty for third parties).

The Court also identifies a consistency of approach with much earlier English cases, indicating that variants must “be not material to the principles and substance of the invention or

“to have taken and adapted the substance of the invention” or “taken the pith and marrow.”

As always, the issues are to be addressed from the standpoint of a person skilled in the art.

In contrast to the ‘old’ infringement test, which recognised equivalents as a principle of construction and focussed on the claims, the new test introduces a standalone doctrine of equivalents covering immaterial variants that achieve the same result as the patented invention in substantially the same way.

Article 69 and the Protocol

Article 69 of the EPC 2000 provides that the extent of protection conferred by a European patent “shall be determined by the claims” but “nevertheless, the description and drawings shall be used to interpret the claims”.

Article 1 of the Protocol provides that a patent must be interpreted as defining a position between two extremes (where the claims are given a strict literal meaning or only serve as a guideline) which combines a fair degree of protection for the patent proprietor with a reasonable degree of legal certainty for third parties).

Article 2 provides that “due account shall be taken of any element which is equivalent to an element specified in the claims”.

New Variants

The reformulated second Protocol question has lowered the bar for patentees in two significant ways:

- (i) variants that are not foreseeable at the priority date but which subsequently become obvious (based on the Common General Knowledge) as at the date of infringement may infringe by equivalence and

- (ii) the person skilled in the art is now assumed to know that the variant works (to the extent it actually does work) leaving that addressee only to consider if it was obvious that it does so in substantially the same way as the invention.

This reformulation seems to align with the approach taken in Netherlands where it is considered contrary to fair protection to limit infringement by equivalence to variants that are foreseeable at the priority date, on the basis that developments and techniques may become available after the priority date, which the patent drafter would not have been able to take into account but nevertheless fall within the inventive concept.

Before the *Actavis v Eli Lilly* case reached the Supreme Court, the High Court and Court of Appeal, applying the old *Improver* guidelines, concluded that it would not have been obvious at the priority date of Eli Lilly's patents that using a different form of pemetrexed would have no material effect, thereby leading to findings in both courts of no infringement (see box for The Background to the case). It may well have led to a different result in the *Improver* case.

The shift in emphasis from the wording of the claims to "immaterial variants" however invokes a corresponding focus on identifying the "inventive concept". In practice this can be an uncertain, and sometimes subjective exercise. A common challenge is identifying the appropriate level of generality or technical detail at which to assess what constituted the inventive step.

Impact on Validity

Validity was not an issue in the case but the judgment raises questions there too. However, while the scope of protection has been extended by the expansion to equivalents, it is not clear that an "equivalent" that formed part of the prior art would invalidate the patent claim as properly construed.

Background to the Case

The issue in the appeal was whether three medical products manufactured by the Actavis group of companies ("Actavis") would infringe an Eli Lilly European Patent (UK) and its corresponding designations in France, Italy and Spain.

The patented invention relates to the administration of the pemetrexed disodium chemical as a therapeutic cancer treatment. Specifically, when this chemical is administered in combination with vitamin B12, its damaging side effects are eliminated. This medicament has been successfully marketed by Eli Lilly under the brand name Alimta® since 2004.

Actavis' three generic products each contain a variant of the pemetrexed disodium compound (pemetrexed diacid; pemetrexed ditromethamine and pemetrexed dipotassium) combined with vitamin B12. In order to clear the way, Actavis applied for a declaration of non-infringement in respect of Eli Lilly's UK patent and its designations. Eli Lilly brought a counterclaim for infringement.

Increased Relevance of the Prosecution File

The English courts have previously regarded the prosecution history as generally not relevant to interpretation of a patent. However, Lord Neuberger (who gave the leading judgment) concluded that the UK courts should 'adopt a sceptical, but not absolutist, attitude' to use of the prosecution file, suggesting it will only be appropriate to consult it in very limited circumstances. This would be where (i) the contents clearly resolve ambiguity relating to a point at issue or (ii) it would be contrary to public interest to ignore the contents of the file (for example, if the patentee has made it clear in its communications to the EPO that it was not

seeking a monopoly upon grant that covered the variant the patentee now claims to be infringing).

Taking this approach, the Supreme Court held that the prosecution history, which showed that Eli Lilly had narrowed the patent claims, could not be relied upon (Lilly had narrowed the claims to the use of pemetrexed disodium rather than antifolates (the broader class of chemical to which pemetrexed belongs)) in response to objections from the examiners of clarity/sufficiency and subsequently added matter but reserved its position in relation to future divisionals which might be wider.

The Court suggested the examiner was wrong to limit the claims to pemetrexed disodium because the teaching of the specification did not expressly extend to other antifolates. In any case, the court considered that irrelevant on the basis that the whole point of the doctrine of equivalents was that it entitles a patentee to extend the scope of protection beyond the ambit of the claims.

The finding on this point should provide patentees with comfort that if they deliberately accept narrow claims during prosecution they may still be able to argue for a broad construction of those claims at a later date for the purpose of infringement, even if the relevant objections were not challenged or appealed by the patentee. This contrasts with the US where the patentee must appeal from an examiner's decision of this sort or may find that a court deciding an infringement claim will be stuck with the limitation. That said, the specific language used will be important so patentees should think carefully about the content of their communications with the Patent Office (particularly statements supporting claim amendments) as part of the prosecution.

The result

Applying the new *Improver* questions, the court found there was no doubt that the Actavis products (i.e. pemetrexed dipotassium) would work in the same way as the invention (all

ultimately involving a medicament containing pemetrexed anion and vitamin B12) - achieving substantially the same result in substantially the same way as the invention (i.e. essentially use of pemetrexed disodium).

The Supreme Court concluded that it was clear that the notional addressee of the patent would appreciate that the Actavis products would work in the same way and that it was a routine exercise to try the known alternatives. In contrast to the Court of Appeal, the Supreme Court concluded that the addressee should be treated as being aware that the Actavis products **did** work - so the question was simply whether it would have been obvious that they did. This marks a significant change in approach given that testing whether an alternative salt or compound will work in the same way may require considerable work, and work that the patentee has not done.

Although the experiments described in the patent were only done on the disodium salt, the specification included broader teaching and the court concluded that it was very unlikely a notional addressee would think the claims limited to pemetrexed disodium.

Harmonisation in Europe

The decision inevitably involved a comparative analysis of the law of infringement in a number of key European patent jurisdictions since a declaration of infringement was sought in relation to a number of key patent jurisdictions (see Box "Background to the Case"). There is a strong flavour in the judgment of a desire to work towards consistency throughout Europe, perhaps in part in anticipation of the Unified Patent Court System being introduced (assuming it survives Brexit).

The impact of the new test

The practical application of the test will become clearer as the courts apply it to new facts. Meanwhile, some conclusions as to infringement

risk or potential claims may be merit reassessment.

The case was discussed at an event organised by Sir Robin Jacob at UCL's Institute of Brand and Innovation Law in London on 1 November, attended by more than 700 people, including most of the IP Bar.

The illustrious panel included Lord Neuberger (this was his last Supreme Court judgment before retiring) and Lord Sumption, who was part of the panel for the Appeal. While the judges were of course limited in the extent that they could

comment on the case, there was a clear sense that they were aware of the implications and that it indeed marks a new approach which is here to stay. The other members of the panel were judges from Germany, Holland and the US: Prof Dr Peter Meier-Beck of the German Federal Supreme Court, Judge Rian Kalden of the IP Division of the Dutch Court of Appeal, and Judge Kate O'Malley of the US Federal Circuit Court of Appeal. All seemed enthusiastic about the decision and there was a sense that things had generally moved on since the *Improver* case was decided (with different results across Europe) and that harmonisation was more successful now.



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