In view of the UK Supreme Court’s judgment in Actavis v Eli Lilly, when will an 'equivalent' infringe as an immaterial variant? How does this compare with the law regarding equivalents in France and Germany? And would a court in France or Germany reach the same conclusion as Lord Neuberger?

In a landmark decision (Actavis v Eli Lilly), the UK Supreme Court has re-steered the law of patent infringement in the UK, stating that there is a doctrine of equivalents. As explained in our introductory article on the decision, Lord Neuberger, stated ([54]):

“...a problem of infringement is best approached by addressing two issues, each of which is to be considered through the eyes of the notional addressee of the patent in suit, i.e. the person skilled in the relevant art. Those issues are: (i) does the variant infringe any of the claims as a matter of normal interpretation; and, if not, (ii) 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 an infringement; otherwise, there is not.

What exactly does this mean?

Limb (i) is considered in our article titled Actavis v Eli Lilly - What is "normal interpretation"?

In this article, we consider limb (ii), specifically, how does the Supreme Court suggest that a question of infringement by so-called equivalence be assessed? We also consider how this UK doctrine of equivalents compares with the law regarding equivalents in France and Germany, and consider whether the courts in France and Germany would have reached the same conclusion as Lord Neuberger.
The law in the UK

Limb (ii) is not a question of construction

After equating the meaning of the words "construction" and "interpretation" (paragraph 53), Lord Neuberger said of limb (ii) (also referred to as "issue (ii)"):

"...so long as the issue [of infringement] is treated as one of interpretation, it will lead to a risk of wrong results in patent infringement cases and it will also lead to a risk of confusing the law relating to the interpretation of documents. In my opinion, issue (ii) involves not merely identifying what the words of a claim would mean in their context to the notional addressee, but also considering the extent if any to which the scope of protection afforded by the claim should extend beyond that meaning. As Sir Hugh Laddie wrote in his instructive article Kirin-Amgen - The End of Equivalents in England? (2009) 40 IIC 3, para 68, "[t]he Protocol is not concerned with the rules of construction of claims" but with "determining the scope of protection".

What is it that makes a variation "immaterial"?

When considering what makes a variation "immaterial", Lord Neuberger considered that the three questions formulated by Hoffmann J (as he then was) in Improver v Remington [1990] FSR 181 provide helpful assistance but needed some reformulation. The reformulated questions, and Lord Neuberger's key reasoning in respect of them, are discussed below.

The first question

"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?"

Lord Neuberger said that the emphasis here is on how "the invention" works. The court should focus on the "the problem underlying the invention", "the inventive core", or "the inventive concept" as it has been variously termed in other jurisdictions.

Compared with the original first Improver question, Lord Neuberger's re-wording crucially shifts the focus away from assessing the invention as set out in the claims towards identifying the inventive concept of the patent.
The second question

"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?"

Lord Neuberger said that the question should be asked on the assumption that the notional addressee knows that the variant works to the extent that it actually does work. This, said Lord Neuberger, is a fair basis on which to proceed in terms of balancing the factors identified in article 1 of the Protocol (which is reproduced in our introductory article here), consistent with the approach of the German, Italian and Dutch courts, and also consistent with the fact that the notional addressee is told (in the patent itself) what the invention does.

Compared with the original second Improver question, this is a lowering of the burden on the patentee seeking to establish infringement. In the original question, it was a requirement (for the patentee seeking to establish infringement) that it would have been obvious, at the date of publication of the patent to a reader skilled in the art, "that the variant had no material effect". This required the addressee to figure out for himself whether the variant would work.

The facts of the present case illustrated why this was too strict a test: because a chemist would not be able to predict the effect of a substitution for the sodium counter-ion without testing at least the solubility of the active ingredient in the Actavis products, it was not possible to predict in advance whether any particular counter-ion would work. Therefore the case on infringement fell at the original second Improver question. However, salt screening was a routine exercise in determining suitability, and the chemist would be reasonably confident that he would come up with a substitute for the sodium counter-ion. In those circumstances, given that the inventive concept of the patent was the manufacture of a medicament which enabled the pemetrexed anion to be administered with vitamin B12, the application of the second Improver question failed to accord "a fair protection for the patent proprietor" as required by article 1 of the Protocol.

Lord Neuberger said that the reformulated second question should also apply to variants which rely on, or are based on, developments that have occurred since the priority date, even though the skilled addressee is treated as considering the second question as at the priority date.

There is no requirement for the variant not to be inventive. It may be that the infringer is
entitled to a new patent, but that is "no reason why the variant should not infringe the original patent".

**The third question**

"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?"

Lord Neuberger made a number of points intended to explain how this question should properly be answered.

First, although the language of the claim is important, consideration is not excluded of the specification of the patent and all the knowledge and expertise which the notional addressee is assumed to have.

Second, the fact that the language of the claim does not on any sensible reading cover the variant is not enough to justify holding that the patentee does not satisfy the third question. In other words, the fact that the variant is not within the "normal interpretation" of the claim and so does not infringe pursuant to limb (i) of Lord Neuberger's test, does not prevent the skilled reader of the patent from concluding that the patentee did not intend that strict compliance with the literal meaning of the claim was necessary, and therefore from concluding that the variant infringes pursuant to the doctrine of equivalents. This is common sense; if it were otherwise, it is difficult to imagine any scenario in which the doctrine of equivalents might be found to apply.

Third, it is appropriate to ask whether the component at issue is an "essential" part of the invention, but that is not the same thing as asking if it is an "essential" part of the overall product or process of which the inventive concept is part. In Lord Neuberger's view, in the Improver case, Hoffmann J "may" have wrongly considered the latter question.

Fourth, when one is considering a variant which would have been obvious at the date of infringement rather than at the priority date, it is necessary to imbue the notional addressee with rather more information than he might have had at the priority date.

**Limb (ii) infringement in the Actavis v Lilly case**

As discussed in our introductory article, Lord Neuberger proceeded to consider whether,
in the present case, Actavis' proposed products would infringe Eli Lilly’s patent by answering the reformulated Improver questions. His tentative conclusion was that the doctrine of equivalents applied. However before deciding the point conclusively, he turned to the prosecution history.

The law on recourse to the prosecution history in the UK and its impact in the analysis of infringement

In support of its case of non-infringement, Actavis relied upon the prosecution history of the patent. This gave rise to a question of general application: whether, and if so when, is it permissible to have recourse to the prosecution of a patent when considering whether a variant infringes that patent?

Lord Neuberger’s conclusion is set out in our introductory article. In short, he said that reference to the prosecution history should be restricted to certain limited cases i.e. (i) when the point at issue is truly unclear if one confines oneself to the specification and claims of the patent and (ii) when it would be contrary to the public interest for the contents of the file to be ignored.

Turning to Eli Lilly’s prosecution file, he said that it did not justify departing from the preliminary conclusion that the patent would be infringed, given the specific circumstances surrounding the prosecution history. Indeed, in paragraph 89 he expressed the view that the examiner had been wrong in raising the objections (based on disclosure and clarity, and then extent of protection) following which Eli Lilly had narrowed its claim language to pemetrexed disodium.

Accordingly, Lord Neuberger concluded that the Actavis products would directly infringe Eli Lilly’s patent.

The law in France

The doctrine of equivalents in France

The French Intellectual Property Code implements Article 69 (1) of the European Patent Convention (EPC). Article L. 613-2 of the Code provides that “the extent of the protection conferred by a European patent or a European patent application shall be determined by the claims. Nevertheless, the description and drawings shall be used to interpret the claims".
In addition, the guidelines provided by the 2000 Protocol on the Interpretation of Article 69 EPC (the Protocol) state that equivalents should be taken into account when assessing the extent of patent protection. The guidelines have not been transposed into French law but the doctrine of equivalents has been progressively defined by French judges putting into practice the rationale expressed in the Protocol. The courts have held that the application of the doctrine of equivalents cannot result in an excessive protection for the patentee, whereas an infringer should not be able to avoid condemnation by the sole adoption of equivalent means[1].

Under the French doctrine of equivalents, a patent is deemed to have been infringed where a different means is used to perform the same function in order to reach an identical or similar result[2]. The function is defined as the first technical effect produced by the execution of the claimed means, whereas the result is constituted by the practical advantages achieved by the invention[3]. For example, a claim to a motorbike helmet with a peg was found to be infringed under the doctrine of equivalents by a motorbike helmet with a slot. This was because the infringing helmet would perform the claimed function i.e., guiding the chinstrap through the rotation, in order to reach the same result, that being to make it follow a trajectory which was not completely round[4].

The jurisprudence has consistently stated that when the function of a particular claimed means was not known in the prior art and an alleged infringing means of a different form performs the same function, there is infringement by equivalence[5]. Conversely, there is no infringement by equivalence if the function of the claimed means is not new, in which case the scope of protection should be limited to the claimed means[6].

**Would a court in France reach the same conclusion as Lord Neuberger in respect of the French designation of Eli Lilly's patent?**

For the reasons explained above, an assessment of the novelty of the function of the claimed means is necessary under the French doctrine of equivalents. In the Actavis v Eli Lilly case, in the context of the French designation of Eli Lilly’s patent, there was a disagreement between the English High Court (Patents Court) and the Supreme Court on this issue.

The first instance judge considered that the patent did not reveal a new function stemming from the use of pemetrexed disodium, and, as a consequence, the doctrine of equivalents could not apply. He focused on the fact that pemetrexed was already known at the priority
date of the patent as having therapeutic effects on cancerous tumours, even though in practice its use as an anti-cancer drug was precluded because of its damaging and fatal side effects.

In the Supreme Court, Lord Neuberger considered that the function of the patent was actually new. He said that the patent disclosed that pemetrexed disodium, when administered with vitamin B12, "could be used for a function for which it could not previously have been satisfactorily or safely used in practice", that being to treat cancerous tumours without such severe side effects. In other words, the patent constituted an improvement compared to prior art, thus the function of the claimed means was new.

There is little case law in France on the application of the doctrine of equivalents in the pharmaceutical industry, so it is difficult to find guidance on the definition of what is a new function. It is worth mentioning though a decision issued in a case involving a patent covering the manufacturing process of a molecule used in a patented drug - the French Supreme Court held that a means enabling a result to be achieved "that was impossible to obtain in prior art" was new in its function[7].

Thus, in the authors' opinion and in light of the aforementioned decision, it appears that the approach taken by Lord Neuberger in respect of the French designation of Eli Lilly's patent, of concluding that the function of the claimed means was new, could be followed by a French judge, who could also conclude that the function of the patent was new and that the doctrine of equivalents should apply. Indeed, French courts could view the patent as performing a new function if, considering the circumstances, it constituted an improvement and an important technical progress having regard to prior art.

However, whether a French court would reach such a conclusion, could be impacted by its consideration of the prosecution history.

The law on recourse to the prosecution history in France and its impact on the analysis of infringement

Lord Neuberger said that "While the French courts appear to be more ready to refer to the prosecution file on issues of interpretation or scope than the German or Dutch courts, it is unclear how much, if any, difference there is in outcome".

In the authors' experience, in practice, where it is invoked by a party, French judges do routinely consider the prosecution history as part of the factual context, both when
interpreting the claim language and when considering whether there is infringement pursuant to the doctrine of equivalents. French judges pay particular attention to any narrowing of the claim(s) in order to avoid any conflict with relevant prior art, and to secure the grant of the patent. If the patentee has expressly stated its intent to narrow down the scope of the patent protection and to limit it to the particular means claimed, the extent of protection of the claim can be expected to be limited to the particular claimed means and the doctrine of equivalents would not apply. But such waiver needs to be explicit, express and unambiguous[8].

As noted above, in the context of the UK designation, Lord Neuberger did take the prosecution file into consideration. In the specific circumstances of the case, he concluded that the file did not justify departing from his initial view that the patent would be infringed.

However, in a decision issued in 2011, the Paris Court of first instance adopted a different approach. The patent claim in issue had been limited after the EPO examiner expressed a view that proposed wording lacked sufficiency and did not have basis in the specification[9]. The judge decided that the claim had to be limited in accordance with the amendments made because of the lack of sufficiency emphasized by the examiner.

Therefore, when considering whether to cast aside the doctrine of equivalents, French courts do not necessarily distinguish between the different reasons justifying the limitation of the claim.

However when considering whether the Actavis products would infringe the French designation of Eli Lilly's patent, Lord Neuberger did not consider whether the French court would take a different approach to the consideration of the prosecution file.

It therefore seems at least possible that in the Actavis v Eli Lilly dispute, a French judge might have limited the extent of protection of the patent to the combination of pemetrexed disodium with vitamin B12 because of the limitations implemented during the examination process, and, in the end, refused to conclude that the Actavis product constituted an infringement by equivalence of Eli Lilly's patent.

The law in Germany

The legislation governing the "scope of protection" of a patent in Germany (both German patents and European patents granted for Germany) is section14 of the German Patent Act (PatG), which reads as follows.

"The extent of the protection conferred by the patent and the patent application shall
The doctrine of equivalents in Germany

The possibility of patent infringement beyond the literal wording of a granted patent claim, equivalent patent infringement, is a well-established legal concept in patent litigation proceedings before German courts. The requirements which have to be fulfilled are laid down in case law, in particular in the decision "Cutting-Blade I" (file No. X ZR 168/00) of the Federal Supreme Court (Bundesgerichtshof, (BGH)). These requirements are:

1. Does the modified means realised by the infringing embodiment have objectively the same effect as the means specified in the claim? *(same effect)*
2. Would the person skilled in the art, using the common general knowledge, have realised at the priority date that the variant has the same effect? *(obviousness)*
3. Are the considerations which the skilled person takes into account for the variant in the light of the meaning of the invention close enough to the considerations taken into account for the literal solution protected by the claims, such that the skilled person will consider the variant as a solution which is equivalent to the literal one? *(parity)*

Since the doctrine of equivalence has a history that goes back to the 1980's, over the years it has been further developed by the Courts, in particular by the BGH.

Would a court in Germany reach the same conclusion as Lord Neuberger in respect of the German designation of Eli Lilly's patent?

The answer is yes and no, and this ambivalent answer stems from the history of the Actavis v Eli Lilly proceedings in Germany.

In short, on 3 April 2014, the District Court Düsseldorf concluded that Actavis' proposed cancer medicament containing pemetrexed dipotassium and vitamin B12 for inhibiting tumour growth would infringe the German designation of Eli Lilly's EP 1 313 508 patent by the doctrine of equivalents. The District Court issued an injunction against Actavis Group
PTC ehf and its subsidiary Actavis Deutschland GmbH & Co. KG.

On 5 March 2015, the second instance Higher District Court Düsseldorf (docket no. I-2 U 16/14) reversed the first instance decision. Contrary to the first instance court, the Higher District Court concluded that Actavis' proposed medicament did not fall within the scope of the doctrine of equivalents.

On 14 June 2016, the Federal Supreme Court (Bundesgerichtshof, BGH) (docket no. X ZR 29/15) annulled the judgment of the Higher District Court Düsseldorf and referred the case back to it. The Federal Supreme Court's reasoning included the following:

- There is a difference between the Actavis v Eli Lilly case and former decisions of the BGH (in particular "Okklusionsvorrichtung" and "Diglycidverbindung") in one substantial aspect: Eli Lilly's patent does not disclose two concrete embodiments with only one of them being claimed, but only one relevant concrete - and also claimed - chemical compound, this being pemetrexed disodium (see BGH judgment at para. 55).  
- The Higher District Court was incorrect in ruling that the infringement of Eli Lilly's patent by equivalent means was incompatible with the basic principles set up by the BGH. According to these principles, an embodiment cannot be included in the scope of protection of a patent if the embodiment is not covered by the patent specification (irrespective of the reasons for this) according to the clear wording of the patent specification. This shall even be the case if the embodiment is disclosed or detectable for persons skilled in the art. Further, the BGH points out that a patent infringement with equivalent means is usually denied if the patent specification reveals several possibilities of how a certain technical effect can be achieved but only one of these possibilities has been included in the patent claim.

It is also noteworthy that the Higher District Court's conclusion in its Actavis v Eli Lilly judgment that the disclosure of a category of chemical compounds has the same legal effect as listing all chemical compounds belonging to the category is inconsistent with more recent jurisprudence from the BGH in the decisions "Okklusionsvorrichtung" and "Diglycidverbindung. Pemetrexed dipotassium is not explicitly stated in the patent specification. Also, it is not sufficient that pemetrexed dipotassium is an antifolate belonging to the same category as pemetrexed disodium (see BGH judgment at para. 71)).

The Higher District Court Düsseldorf has not yet rendered a new judgement.
The law on recourse to the prosecution history in Germany and its impact on the analysis of infringement

According to s.14 PatG and Art. 69 EPC, the documents the German courts may refer to when interpreting the claims are (limited to) the patent specification, in particular the description and the drawings. According to the legislation, the prosecution file cannot be referred to even in exceptional cases, and thus it plays no role in determining the "extent of protection" of a patent contemplated in Article 69 ("Schutzbereichsbestimmung" in the German version of the EPC).

However, in the Actavis v Eli Lilly case, the Higher District Court Düsseldorf relied on files from the grant procedure in its interpretation of the patent in dispute, and the Federal Supreme Court rejected Eli Lilly's complaint in this respect. The Federal Supreme Court ruled that according to the case law of the court it is admissible to refer to a statement of the patent applicant as an indication of how the person skilled in the art would construe the subject matter of the claim. However, statements made in the course of prosecution cannot without further justification be used as the sole basis of interpretation.

The Higher District Court Düsseldorf had taken the examiner's view, that the mention of pemetrexed disodium did not disclose the more general term "pemetrexed" (only), as additional confirmation of the conclusion it had reached for other reasons. The Federal Supreme Court did not consider that the Higher District Court had erred in this respect. However this approach stands in contrast with the tentative expression of opinion by Lord Neuberger that the examiner had been wrong.

Comment

Unquestionably, the Supreme Court's decision in Actavis v Eli Lilly plants a doctrine of equivalents firmly within UK patent law. However, Lord Neuberger said that the reformulated Improver questions remain only guidelines, not strict rules, and that they may also sometimes have to be adapted to apply more aptly to the specific facts of a particular case. It is therefore to be expected that the next decade or two will see continual development of the UK doctrine of equivalents, as litigants push the limits of their cases and the lower courts grapple to further define the law.

If and when the Unified Patent Court (UPC) opens, a harmonised approach to the doctrine of equivalents can be expected to emerge. The approach of the UK Supreme Court in the Actavis v Eli Lilly case, considering and drawing upon higher court jurisprudence from a
number of key European Patent Convention countries, can be expected to be considered, and it may be seen as indicating the future course of UPC law in the area. The approach taken by the courts in other participating countries, including Germany and France, can be expected to be considered also. But it is not just the substantive law in which a harmonised approach will need to emerge; with a view to minimising forum shopping a harmonised procedural approach will be needed also, in respect of which practice regarding recourse to the prosecution history is an example.

It remains to be seen, however, when the UPC will become operational, and the extent to which national courts will align national patent law in accordance with the developing jurisprudence of the UPC.

Linked with all this are important questions as to the impact of the UK Supreme Court’s judgment for patent law and practice in respect of validity, including patent filing strategy. This will be discussed in a forthcoming article.

If you enjoyed this article, you may also enjoy reading Gordon Harris’ article Actavis v Eli Lilly - Should We Have Seen It Coming?

Footnotes:

[1] Emphasized by Lyon Court of First Instance, 13th November 2014, No 07/02964
[3] Paris Court of Appeal, 17th May 2016, No 14/10335
[4] Paris Court of First Instance, 28th January 2016, No 13/10277
[8] Paris Court of Appeal, 4th section, 4th March 2009, No 07/08437, confirmed by French Supreme Court, 23rd November 2010, No 09-15.668
[9] Paris Court of First Instance, 20th September 2011, No 10/02548

NOT LEGAL ADVICE. Information made available on this website in any form is for information purposes only. It is not, and should not be taken as, legal advice. You should not rely on, or take or fail to take any action based upon this information. Never disregard professional legal advice or delay in seeking legal advice because of something you have read on this website. Gowling WLG professionals will be pleased to discuss resolutions to specific legal concerns you may have.
Authors

Céline Bey
Partner - Paris

Email
celine.bey@gowlingwlg.com

Phone
+33 (0)1 42 99 35 44

vCard
Céline Bey

Lydia Birch
Senior Associate - London

Email
lydia.birch@gowlingwlg.com

Phone
+44 (0)20 7759 6934

vCard
Lydia Birch

Gordon Harris
Partner - International IP Leadership, London

Email
gordon.harris@gowlingwlg.com

Phone
+44 (0)20 3636 8063

vCard
Gordon Harris

Ailsa Carter
<table>
<thead>
<tr>
<th>PSL Principal Associate - London</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Email</strong></td>
</tr>
<tr>
<td><a href="mailto:ailsa.carter@gowlingwlg.com">ailsa.carter@gowlingwlg.com</a></td>
</tr>
<tr>
<td><strong>Phone</strong></td>
</tr>
<tr>
<td>+44 (0)20 3636 8092</td>
</tr>
<tr>
<td><strong>vCard</strong></td>
</tr>
<tr>
<td>Ailsa Carter</td>
</tr>
</tbody>
</table>