

Lilly v Actavis - Supreme Court Introduces a Doctrine of Equivalents in the UK

The UK Supreme Court's judgment in Lilly v Actavis has profound implications for the scope of protection provided by patent claims in the UK.

The judgment moves away from the principle that the patentee should enjoy the full extent, but no more than the full extent, of the monopoly that a reasonable person skilled in the art, reading the claims in context, would think he was intending to claim. Rather, following this new decision, a patent claim in the UK can be infringed by products or processes that are not within the ambit of the language used in the claims.

Legal background

The legislative provisions governing the scope of protection conferred by a patent in the UK are governed, as in the other EPC States, by Article 69 EPC and the Protocol thereto. The text of Article 69 EPC and its Protocol are set out in the Annex.

Article 2 of the Protocol requires that "due account" must be taken of any element that is "equivalent" to an element specified in the claims. However, the UK courts have long been reluctant to recognise a doctrine of equivalents, in the sense that a claim should protect subject matter that is different from, but equivalent to, that specified in the claim. Rather, the courts have applied a doctrine of "purposive construction", in which they seek to determine what the person skilled in the art would have understood the patentee to be using the language of the claim to mean.

The leading case explaining this approach of purposive construction was House of Lords case Kirin-Amgen v TKT¹. That case involved a claim for recombinant erythropoietin, prepared in a eukaryotic host cell.

In Kirin-Amgen v TKT, the court noted that other jurisdictions, such as the United States, did apply a doctrine of equivalents, but opined that such a doctrine was "born of despair" and that the correct approach was simply to assess what the person skilled in the art would have understood the patentee to be claiming. On the facts of the case, the court held that a skilled person would understand a "host cell" to be a cell that is host to a foreign DNA sequence that encodes erythropoietin or an erythropoietin analogue. TKT's product was not prepared via such a cell, and therefore did not infringe.

Facts and history of the present case

The claims of Lilly's patent related to the use of the disodium salt of pemetrexed in the manufacture of a medicament for use in combination with vitamin B12 for the treatment of cancer. A corresponding medicament including pemetrexed disodium and

the vitamin (Alimta®) had been successfully marketed by Lilly since 2004. In order to clear the way for marketing of competing products, Actavis applied for declarations of non-infringement in relation to various pemetrexed products comprising the diacid (non-salt) form of pemetrexed or alternative salt forms to disodium (such as dipotassium).

Actavis' position was that their products should not infringe directly because in no sensible way could pemetrexed dipotassium (for example) be said to fall within the expression "pemetrexed disodium" as recited in claim 1 of the patent. Given the background outlined above, and following Amgen v TKT, Actavis could reasonably have expected the courts to take the view that there was no direct infringement of Lilly's patent, and indeed the first instance court and the Court of Appeal did just that. In the UK it is, though, possible to ask the Supreme Court to hear an appeal from a ruling from the English Court of Appeal on a point of law of general public importance, and in this instance the Supreme Court agreed to hear such an appeal.

Direct infringement

On appeal, the Supreme Court recognised that the expression "pemetrexed disodium" set out in claim 1 of the patent could not in any sensible way be interpreted so as to cover, for example, pemetrexed dipotassium. However, contrary to the reasoning in Amgen v TKT, the court then held that this should not be the definitive question for determining infringement. Rather, Lord Neuberger, who gave judgment for the court, ruled that a variant that is not covered by the claims as a matter of normal interpretation could nevertheless infringe if it varies from the claimed invention only in an immaterial way.

In reaching this conclusion, the judge noted that Article 2 of the Protocol to Article 69 EPC makes it clear that there is potentially a difference between the interpretation of a claim and the extent of protection conferred by the claim and that, when assessing that difference, equivalents must be taken into account. He also reviewed relevant case law in other EPC states (Germany, France, Italy, Spain and the Netherlands), and noted that many of these states already apply a doctrine of equivalents.

A new three-part test for determining whether a variant outside the normal meaning of the claims can infringe was then set out. The three questions to be answered 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, i.e. the inventive concept revealed by the patent?

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 effect 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?

It is noteworthy that the first question refers to the “inventive concept revealed by the patent”. The judge did not explain in detail what is meant by the “inventive concept”. He viewed it as requiring consideration of how the invention works, and equated it to terms he identified from other EPC jurisdictions, including a consideration of “the problem underlying the invention” and “the inventive core”. Presumably, identification of the “inventive concept” should involve an assessment of the features central to distinguishing the invention over the prior art.

The second question requires an assessment of whether at the priority date of the patent it would be obvious that the variant achieves substantially the same result in substantially the same way as the invention. The judge held that it was important that the knowledge that the variant exists, and that it achieves substantially the same effect, must be ascribed to the skilled person before the question is asked. It follows that it is possible to have an affirmative answer to the second question even where the variant was unforeseeable at the priority date.

As regards the third question, the judge clarified that the relevant issue is whether or not the feature at issue is essential to the “invention”, not whether or not it is essential to the product or process of which the inventive concept is part. For example, a distinction can be drawn between features that contribute to the inventive concept and conventional features that are merely essential to the operation of a particular product or process that embodies the inventive concept (e.g. a conventional wheel might be an essential component of a new and inventive bicycle, but not essential to the corresponding “invention”).

The judge further held that the third question should be considered in the light of the specification as a whole and the knowledge and expertise of the skilled person. He also pointed out that the fact that the language of the claim excludes the variant on any sensible reading is not enough to justify the answer “yes”. Finally, he emphasised that it is necessary to imbue the skilled person with the knowledge of the variant and the fact that it achieves substantially the same effect as the claimed invention when assessing the third question.

Application of the test

On the facts of the case, the first question was answered positively on the basis that all of Actavis’ products worked in the same way as the invention, involving a medicament that is a combination of pemetrexed and vitamin B12. The judge defined the inventive concept of the patent as the manufacture of a medicament which enables the pemetrexed anion to be administered with vitamin B12.

The second question was also answered affirmatively since it was held that it would be appreciated at the priority date that the Actavis products would work in the same way as pemetrexed disodium when administered with vitamin B12. Earlier findings of fact had been made in the first instance Patents Court judgment

to the effect that the preparation of other suitable salt forms of a given molecule would not be a predictable exercise. However, the second question presupposes knowledge that the particular variants in question are indeed functional, i.e. they achieve substantially the same result as the invention.

Finally, the third question was answered in the negative on the basis that the specification did not teach any essentiality to the disodium salt of pemetrexed, but rather contained a more general disclosure of antifolates and their administration with vitamin B12. Also, there was a finding that the skilled person would know, as a matter of common general knowledge, that different salt forms may be used and screened for routinely in drug development. The fact that the particular specific disclosure of the patent and its examples related only to pemetrexed disodium did not justify, in the view of the judge, the conclusion that the patentee intended to limit the scope of protection of the granted patent to this salt form only. In this regard, the judge drew a clear contrast between the disclosure of the specification of a patent and the scope of protection provided by the claims.

The judge thus concluded that, subject to a consideration of the prosecution history, the Actavis products infringe claim 1 of the patent.

Consideration of prosecution history

The judge generally held that contents of a prosecution file should be treated with some scepticism. However, he held that a reference to the file would be appropriate if:

1. the point at issue is truly unclear if one confines oneself to the description and claims of the patent, and the contents of the file unambiguously resolve the point; or
2. it would be contrary to the public interest for the contents of the file to be ignored.

An example of a situation arising under (ii) may, for example, be where a statement had been clearly made by the patentee that the scope of the claims do not extend to the relevant variant now claimed to be infringing.

The review of Lilly’s prosecution of the application at the European Patent Office established that limitations had been made to original broader claims relating to antifolates generally, in response to objections of lack of disclosure (Article 83 EPC) and lack of clarity (Article 84 EPC). A claim to pemetrexed generally had then been further limited to pemetrexed disodium on the basis of an objection of added subject matter (Article 123(2) EPC).

The judge noted that these limitations had been made to address objections based on the disclosure of the patent, and held that they were not relevant to the question of whether pemetrexed salts other than disodium should be within the scope of the patent pursuant to a doctrine of equivalents. It is possible, of course, that a different conclusion would have been reached if the limitations had been necessary to distinguish the claimed invention from prior art cited by the Patent Office Examiner.

For the reasons given above, all of Actavis’ products were held directly to infringe Lilly’s patent, as being immaterial variants of the claimed invention.

Other infringement findings

Given the findings on direct infringement, the debate on indirect

infringement became moot. However, Actavis were also held to be liable under Section 60(2) of the UK Patents Act as supplying means essential for putting the invention into effect, on the basis that the Actavis products would inevitably be dissolved in saline, which would lead to a dissolved sodium salt of pemetrexed.

Findings of infringement were also made for Actavis' products under French, Italian and Spanish law based on the original application made for the UK court to determine infringement in these jurisdictions, and applying the doctrine of equivalents provisions that exist in these EPC states.

Comment

The Supreme Court's judgment significantly changes previous UK practice for assessing infringement. It has the effect of bringing UK law more in line with other European countries and so may be viewed as a nod towards the Unitary Patent system in which a more harmonised approach to infringement will be required.

Given this development in the law in the UK, it may be appropriate for both patentees and those seeking to develop new products and processes to review any advice they have previously received on infringement, based on the previous *Amgen v TKT* precedent. It may be that a different conclusion could be reached on the same facts following this new judgment.

When drafting and prosecuting patent applications, it may now be more important to include disclosure in the specification relating to the nature of the invention that is framed at a general level. This can then be used for assessing the inventive concept. It also remains important to avoid unnecessary suggestions that particular features are essential to the working of the invention.

If you would like to discuss the impact of this decision on any specific situation you face, please do not hesitate to contact your usual J A Kemp contact.

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ANNEX

Article 69(1) EPC and Protocol Thereto

Article 69(1) EPC:

The extent of the protection conferred by a European patent or a European patent application shall be determined by the terms of the claims. Nevertheless, the description and drawings shall be used to interpret the claims.

Protocol:

Article 1: General principles

Article 69 should not be interpreted in the sense that the extent of the protection conferred by a European patent is to be understood as that defined by the strict, literal meaning of the wording used in the claims, the description and drawings being employed only for the purpose of resolving an ambiguity found in the claims. Neither should it be interpreted in the sense that the claims serve only as a guideline and that the actual protection conferred may extend to what, from a consideration of the description and drawings by a person skilled in the art, the patentee has contemplated. On the contrary, it is to be interpreted as defining a position between these extremes which combines a fair protection for the patentee with a reasonable degree of certainty for third parties.

Article 2: Equivalents

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.

Footnotes

1. *Kirin Amgen v Hoechst Marion Roussel* [2004] UKHL 46 ([2005] RPC 169). The judicial function of the House of Lords was succeeded by the Supreme Court in 2009.

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