House of Lords Clarifies English Law on Patent Infringement

In the most significant patent decision in a number of decades the House of Lords in *Kirin-Amgen* has to some extent rewritten the law on patent infringement. The House firmly aligned the English approach with harmonisation of patent law throughout Europe, drawing a distinction between the European and American approaches to analysis. While the test for infringement has been clarified, it marks quite a change in emphasis and of necessity the issues to be considered in the test involve difficult judgment calls. It will take some time to see how it is likely to be applied by the courts in practice.

**Facts**

*Kirin-Amgen* Inc (Amgen) was the proprietor of a European patent relating to the production of erythropoietin (EPO), a protein made in the kidney that increases the body’s production of red blood cells. The discovery by Amgen of a method of making EPO artificially for use as a drug was a significant advance in the treatment of anaemia, particularly when associated with kidney failure. Amgen marketed it under the name Epogen and the patent (which has subsequently expired) has been very profitable.

The patent described a method of making EPO by recombinant DNA technology and involved the introduction of an exogenous DNA sequence (ie one originating from outside the cell) coding for EPO into a host cell. The DNA sequence is the genetic code for the EPO protein which directs the cell to produce EPO. The host cell containing the EPO DNA then “expressed” that gene, producing the EPO protein.

A dispute arose between Amgen and Transkaryotic Therapies Inc (TKT) and Hoechst Marion Roussel (HMR). TKT, a US corporation, developed a method of making EPO by activating the endogenous DNA sequence coding for EPO which existed in a human cell but which would not ordinarily express it. TKT achieved expression by introducing the necessary control sequence upstream of the EPO gene. TKT’s technique, known as homologous recombination, was not known at the date of the patent in suit. HMR, a UK company, was proposing to import the EPO produced by TKT into the UK.

In summary, the Amgen EPO was made by adding the DNA sequence to a host cell by genetic engineering (ie using DNA exogenous to the cell) and the TKT EPO was made by a gene activation method in which the DNA was already present in the cell (endogenous to it) and was simply switched on (though the DNA relating to the switch was exogenous to the cell).

The relevant claims of Amgen’s patent were for:

(i) a DNA sequence for use in securing the expression of EPO in a host cell (claim 1);

(ii) EPO which was the product of the expression of an exogenous DNA sequence (claim 19); and

(iii) EPO which was the product of the expression in a host cell of a DNA sequence according to claim 1 (claim 26).

Because TKT did not make any EPO in the UK, the alleged infringement was by importation: only claims 19 and 26 were therefore allegedly infringed.

The trial judge, Neuberger J, found that claim 19 was invalid for insufficiency but that claim 26 was valid and infringed. The Court of Appeal held that both these claims were valid, but that neither was infringed. Amgen appealed against the decision that there was no infringement, while TKT and HMR appealed against the finding of validity.
Traditional approach of the English courts

Until the Patents Act 1977, which gave effect to the European Patent Convention (EPC), English statute law did not stipulate the extent of protection conferred by a patent. The traditional English law rules of construction required the words and grammar of a sentence to be given their “natural and ordinary meaning”, which was to be adopted regardless of the context or background against which those words were used unless they were ambiguous and capable of bearing more than one meaning.

British courts gradually moved away from these narrow rules of construction and, in Catnic Components Ltd v Hill & Smith [1982] RPC 183 (a case decided under the pre-1977 law), Lord Diplock recognised that the language used in a patent is sensitive to its context and held that a patent specification should be given a purposive construction and not a purely literal one.

As to inventions which have an equivalent effect to the patent, the doctrine of infringement by use of the “pith and marrow” of the invention was traditionally applied to prevent circumvention of the claims of the patent by an immaterial variant. It was unclear whether the courts regarded this as a principle of construction or as an extension of protection outside the claims, similar to the “doctrine of equivalents” approach taken in the United States.

In Catnic, Lord Diplock offered a new solution and held that the relevant question is whether a person skilled in the area of work in which the invention was intended to be used would understand that strict compliance with a descriptive word or phrase appearing in the claim was intended by the patentee to be an essential requirement of the invention. If so, any variant would fall outside the monopoly claimed, even though it could have no material effect on the way the invention worked.

The impact of European Law

The EPC deals expressly with the extent of protection granted by a patent. The most important provision of the EPC for these purposes is Article 69, which applies to infringement proceedings in the domestic courts of all Contracting States:

“The extent of protection conferred by a European patent or a European patent application shall be determined by the terms of the claims. Nevertheless, the descriptions and drawings shall be used to interpret the terms of the claims.” [emphasis added]

Guidance as to the application of Article 69 is provided by the Protocol on the Interpretation of Article 69, which states that an approach should be taken which lies between the purely literal construction of the patent claims and the use of the claim only as a guideline. Both Article 69 and the Protocol are given effect in English law. This requires a balance to be struck between a construction which gives:

> fair protection to the patentee and

> a reasonable degree of certainty to third parties, who might wish to avoid infringement.

There has long been debate about whether the purposive approach set out in the Catnic case is wholly in accordance with the approach set out in the Protocol. As a result there has been some inconsistency in the UK courts’ approach to patent infringement. While the courts have sometimes applied the test laid down in Article 69 interpreted in accordance with its Protocol, the court has more often applied the principle of interpretation of patents outlined by Hoffmann J (as he then was) in a three part test in Improver v Remington [1990] FSR 181, more recently referred to as “the Protocol questions”.

This test consists of a concise summary of Lord Diplock’s guidance in the Catnic case and requires the court to ask itself the following three questions:

1. does the variant (i.e. the feature of the alleged infringement that differs from the feature claimed) have a material effect on the way the invention works?

2. would the fact 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?

3. would the reader skilled in the art nevertheless have understood from the language of the patent that the patentee intended that strict compliance with the primary meaning was an essential requirement of the invention?

The correct test for patent infringement

The House of Lords held in Amgen that the correct approach to take is the test based on Article 69 and its Protocol, the “bedrock” of patent construction and that the Protocol Questions would only apply in special cases:

“The determination of the extent of protection conferred by a European patent is an examination in which there is only one compulsory question, namely that set by article 69 and its Protocol: what would a person skilled in the art have understood the patentee to have used
the language of the claim to mean?  Everything else, including the [Protocol] questions, is only guidance to a judge trying to answer that question.  But there is no point in going through the motions of answering the [Protocol] questions when you cannot sensibly do so until you have construed the claim.” [emphasis added]

Explaining how this test should be applied, Lord Hoffmann (who gave the principal opinion with which the rest of the House agreed) confirmed that Lord Diplock’s purposive construction test in Catnic was consistent with the Protocol.

The Amgen question

According to Amgen the key question is: what would the person skilled in the art, reading the claims in context, have understood the patentee to mean by the language of the claims?

The test is an objective one: in other words what the patentee is understood to have meant, rather than what the patentee actually meant or intended.

The starting point is to identify what the invention actually is. The patent is then to be construed as it would be understood by a person skilled in the art.

According to Amgen, the person skilled in the art will have:

>- the common general knowledge of someone practising in the relevant field; and
>- a basic level of knowledge of patentability – ie sufficient to appreciate that the patentee is trying to describe something new and will be wanting to avoid a risk of invalidity (eg where a claim that is unclear) or is trying to distinguish the invention over the prior art.

The patent is not necessarily to be given the widest possible construction in the light of the prior art, as it may be that the patentee had particular reasons for including a limitation which are not known (for example to deal with an issue raised in a patent office during prosecution).

In contrast with the US, the prosecution or file history relating to the progress of the patent through the patent office is not relevant to the construction of the patent as granted.

The language used will usually be of critical importance. The House of Lords has brought construction of patents in line with that of other documents, holding that patents must be construed in the light of their context and background (in line with the West Bromwich case ([1998] 1WLR896)) and that “[the meaning of words] depends not only upon the words the author has chosen but also upon the identity of the audience he is taken to have been addressing and the knowledge and assumptions which one attributes to that audience”. This contrasts with the earlier approach of only looking beyond the words when there was an ambiguity to resolve.

Lord Hoffmann however recognised that there will be occasions when it will be obvious to the skilled man that the patentee must in some respects have departed from conventional use of language, or used words or phrases in his description that he had not intended to be essential, but such occasions were not expected to occur very frequently.

No European doctrine of “equivalents”

Lord Hoffmann gave a detailed account of the law in relation to equivalents, which deals with cases where an infringer may use immaterial variants to avoid the scope of the patent claims. The House firmly distinguished the European approach from the US doctrine. This is an issue of some relevance in this case (as it often is) as patent litigation has also been pending for some time between the parties in the US. The US approach first gives the patent claims a literal interpretation and then determines the extent of protection surrounding the claims. This is given effect by the doctrine of equivalents which in effect extends protection to infringements which might be said to be “stealing the benefit” of the invention by performing substantially the same function in substantially the same way to obtain the same result. The effect of this is contained by file wrapper estoppel which essentially prevents a patentee from claiming some protection that was given up during prosecution of the patent.

The House of Lords in Amgen confirmed that in England the claims have a central role (and noted that that was now acknowledged in other European member states such as Germany and the Netherlands where the claims had previously been regarded as a point of departure). In England the claims are to be given a purposive construction, as they would be understood by a person skilled in the art, but this does not equate to extension of protection outside the claims.

The Protocol or Improver Questions

Significantly, the House drew a strong distinction between the Protocol – which is universally applicable - and the Protocol questions which, being merely “guidelines”, are more useful in some cases than in others.

Lord Hoffmann maintained that the Protocol questions can only usefully be answered once the claims of the patent have been construed as required by
Article 69 and its Protocol. The Protocol questions which have been regularly regarded as the key test for infringement are now considered to be relevant only in some cases, in particular in relation to patents involving the use of figures, measurements and angles, or where there is an argument that words may have an alternative looser meaning. They are unlikely to apply to areas of new technology.

**Applying the law to the facts**

Applying these principles of patent interpretation to the facts of the case, Lord Hoffmann considered that the relevant question was whether the person skilled in the art would understand “host cell” to mean a cell which is host to an exogenous DNA sequence which coded for EPO inserted into a cell. The alternative, proffered by Amgen, was that it could include a sequence which is endogenous to the cell, like the human EPO gene which expresses EPO through a method of gene activation, as long as the cell is host to some exogenous DNA.

The House held that the invention of the patent was a particular method of producing EPO (by expression of exogenous DNA in a host cell) and not simply the DNA sequence coding for DNA. On that basis, the person skilled in the art would not understand the claim to cover an alternative method of producing EPO that was not known at the time.

In such circumstances, the Protocol questions were inappropriate and either caused confusion or simply provided a formal justification for the conclusion which has already been reached.

Agreeing with the Court of Appeal decision, Lord Hoffmann held that the claims of Amgen’s patent were insufficiently general to include TT’s new technology for making EPO.

**The invalidity issue**

(1) “Product-by-process” claims

While claim 1 of Amgen’s patent related to the process for producing EPO, claim 26 related to EPO produced by way of the patented process.

Lord Hoffmann explained that the English practice of allowing a patent claim for a product forming part of the state of the art, on the ground that it has been made by a new process, was no longer necessary given that the EPC allows a patentee to rely directly on his process claim to allege infringement of a product made by that process.

The European Patent Office (“EPO”) will only accept a claim to a product defined in terms of its process of manufacture when the product is new in the sense of being different from any existing product in the state of the art but where the difference cannot be described in physical or chemical terms.

The House found that claim 26 was anticipated and therefore invalid.

(2) The EPO and the English courts

Comments made by the House also suggest it is encouraging the English courts to make findings consistent with those of the EPO more often that has perhaps been the case. The House indicated that it would be “unfortunate” if the English courts were to uphold the validity of a patent which on identical facts would have been revoked in EPO opposition proceedings.

It will be interesting to see whether this marks a change in practice, with English courts striving to give decisions on validity which are consistent with the approach of the EPO. In the past, the courts have generally taken a notably independent line and on issues such as obviousness there has been considerable scope for different results. However, in recent years, pressure to harmonise further has grown, most notably in the area of software-related patents.

(3) Sufficiency

TKT and HMR also appealed against the Court of Appeal’s rejection of their assertion that the specification was insufficient to support claim 19. The Patents Act 1977 provides that a patent may be revoked if the specification does not disclose the invention “clearly enough and completely enough for it to be performed by a person skilled in the art”.

Lord Hoffmann stated that in order to decide whether the invention has been enabled, it is necessary to identify the invention and decide what it claims to enable the skilled man to do. Claim 19 was held to be insufficient, primarily because the test for distinguishing EPO falling within the claim was based on molecular weight and was not capable of practical application.

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