Managing Intellectual Property
The Global IP Resource

EUROPE'S COURTS CONVERGE ON NON-LITERAL INFRINGEMENT

25 February 2005

In the light of recent cases on the scope of patent protection, William Cook, Peter Meyer and Francis van Velsen of Simmons & Simmons compare the approach of the English, German and Dutch courts

In the recent UK case of *Kirin-Amgen v Hoechst & TKT* (October 2004), the House of Lords addressed the assessment of patent infringement in UK courts. A patent claim must be construed by asking what the skilled person would have understood a patentee to mean by the language of the claims, especially of "new technology" patents in areas such as biotechnology. In the UK, the substantive nature of the invention *as claimed* is critical.

In reaching this conclusion, the Court's own view was that its reliance upon the primary importance of the claims, as interpreted in accordance with Article 69 of the European Patent Convention using the Protocol on Interpretation of Article 69, keeps the UK's approach to claim construction close to the trend in Germany, the Netherlands and other continental European jurisdictions. This article explores the similarities and differences between the approaches taken in those countries in greater detail: although the terminology and methodology used in each country to describe its approach differ significantly, all three countries are laying increasing emphasis on the patentee's chosen claim wording. It appears that, at a time when the proposals for a European Community-wide patent system are floundering at inter-governmental level, European convergence on claim construction at court level is already taking place.

The framework for claim construction in Europe

The European Patent Convention (EPC) sets out the fundamental basis for construction of European patent claims. The most important provision is Article 69 of the EPC, which states that:

> 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.

According to the Protocol on the Interpretation of Article 69, this article should not be interpreted "in the sense that the extent of the protection ... 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" which was perceived by most practitioners to be the traditional strict approach of the English courts before 1977, based on obsession with the precise claim wording. Nor should Article 69 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" which, traditionally, was closer to the rather more relaxed approach of the German and Dutch courts, based on loose concepts of the inventive achievement as described by the specification as a whole. On the contrary, Article 69 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".

How this middle ground is interpreted in each of the contracting countries is a matter of national case law.

UK

The settled approach of the English courts between these extremes is to give patent claims a "purposive construction", being what a skilled person would have understood the patentee to be using the language of the claim to mean (*Catnic v Hill & Smith* [1981] FSR 60). The House of Lords approved this general approach in *Amgen*.

Since 1989, the approach has often been broken down by following a three-part set of guidelines

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(the three "Protocol" questions) set out in *Improver v Remington* [1990] FSR 181. Where an alleged infringement contains a variant falling outside the primary, literal or a contextual meaning of a claim, the Court assessed (1) any material difference between the variant and the way the invention works, (2) the obviousness of such difference and (3) whether strict compliance with the literal meaning was essential. It was thought that following these guidelines ensured that claim construction in the UK complied with the provisions of Article 69 and the Protocol.

However, the House of Lords in *Amgen* held that the three "Protocol" questions were no substitute for the fundamental approach under the EPC, being purposive construction as defined above. In fact, whether the Protocol questions will be of use at all will depend on the nature of the invention. They may be of use when claims are defined in terms of parameters (measurements, angles and the like), but they are unlikely to be useful in rapidly developing technologies such as biotechnology. Put simply, if they are used after the proper scope of the claim has already been defined according to a purposive construction, they are unlikely to add anything further. They certainly do not introduce any separate doctrine of equivalents into English law: if something is outside the scope of a claim (purposively construed), it is not an infringement, regardless of whether it is somehow equivalent to the invention.

To illustrate this approach, it is interesting to consider the facts and decision in *Amgen*. Amgen owned a European patent relating to the production of the protein erythropoietin (EPO) by recombinant DNA technology, and sued TKT and Hoechst alleging that TKT's method of making EPO infringed the patent. The Amgen patent related to the introduction of an "exogenous" DNA sequence into a host cell (an exogenous sequence being a sequence originating outside the cell), in which cell EPO would be expressed.

The claims explicitly required the introduction of the exogenous DNA sequence into, and expression of EPO in, a "host cell". There was no dispute that this would cover the introduction into a host cell of an *exogenous* DNA sequence which itself coded for EPO, following which EPO would be expressed in that cell. In fact, this was precisely what Amgen themselves had done in an example cited in the patent. However, in TKT's method, the EPO is expressed by an *endogenous* gene, already naturally present in the cell. This relevant *endogenous* EPO gene is normally inactive, but is switched on by introducing an external control sequence (*exogenous* DNA) upstream of the EPO gene itself, enabling the expression of the EPO protein.

The chief question of construction was whether the skilled person would understand "host cell" to mean only: (1) a cell which is host to (ie. recipient of) an exogenous DNA sequence which coded for EPO (which would mean that TKT's process did not use such a host cell and so did not infringe); or whether it should extend also to (2) a cell which is host to any exogenous DNA, as long as the cell includes an EPO sequence which is endogenous to the cell (which would lead to infringement, as TKT's does use such a cell). In the TKT process, the cell is host to the control sequence and other machinery introduced, but not to an exogenous EPO sequence.

After reviewing much detailed evidence, the House of Lords concluded that the patentee regarded it as essential to its invention that the DNA of which expression was sought should not have its origin in the genome of the host cell. This decision was based entirely upon the meaning of the term host cell, which is wholly dependent on the context of the patent, and in particular the description of the invention in the specification. It followed that TKT's process did not infringe. In the House of Lords' judgment, this is where the analysis should end. The claim had been construed "purposively", and on the facts there was no infringement. It specifically disapproved of any further attempt to apply the Protocol questions over and above that construction. To assess a variant outside the claim as so construed, and ask whether this had a material effect on "the way the invention works" as per the Protocol questions, was meaningless. The Court had already, inevitably, looked at the way the invention works when properly construing the claim.

In theory, claims for inventions in rapidly developing fields such as biotechnology may, upon proper construction, cover products or processes that involve the use of technology unknown at the time the claim was drafted. The relevant question for claim construction is whether the person skilled in the art would understand the description in a way that was sufficiently general to include new (future) technology. In *Amgen*, the Court found that it was not - the invention was directed to the particular method of expression disclosed, and not to any method subsequently developed.

Germany

In Germany, the Federal Supreme Court has confirmed and clarified its previous case law on a non-literal infringement in a quintet of decisions of March 12 2002 (cases *Schneidmesser I*, *Schneidmesser II*, *Custodiol I*, *Custodiol II* and *Kunststoffrohrteil*, GRUR 2002, pages 511 - 531). The subject matter of all these cases was how measurements in a claim have to be interpreted. The Federal Supreme Court confirmed that patent infringement has to be ascertained in two steps.

First, the courts have to determine whether or not the alleged infringement constitutes a *literal* infringement of the claims. The courts therefore have to determine the wording of the claims by

identifying its meaning. The test is how the person skilled in the art based on the patent specification would understand the wording of the claims. The reference to the patent specification, and in particular the description contained in the specification, can result in giving a meaning to a word in the claim which is different from its ordinary or its general technical meaning (if for example the patent specification as a whole attributes a different meaning to this word).

If the alleged infringement ("variant") does not *literally* infringe the wording of the claim, the courts have to examine whether they constitute an equivalent infringement. The Federal Supreme Court finds an equivalent infringement where the skilled person, based on considerations that are connected with the meaning of the invention as protected by the claims and his general technical knowledge, considers the variant as an equivalent of the inventive solution. More specifically, the Federal Supreme Court actually identified a three criteria test in the above-mentioned decisions: the court must examine (1) whether the variant solves the problem of the invention with modified *means* which have objectively equal effects, (2) whether the skilled person, based on his general technical knowledge, will find the modified means as having equal *effects* and (3) whether the considerations which the skilled person takes into account for the variant in the light of the meaning of the invention are 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 equal/equivalent to the literal one.

In these decisions, the Federal Supreme Court expressly refers to the *Catnic* case in the UK and states that its own decision is in agreement in principle with *Catnic* and *Improver*. One of the main differences from the UK could be that the Federal Supreme Court stresses very much that in each case the court needs to identify how far the teaching of the patent specification *excludes* considerations that lead to the equivalent solution compared to the literal solution. In this sense, the Federal Supreme Court takes a broader view than the UK as to whether a variant is covered by the patent, as the German court will consider equivalents more readily.

Most of the recent cases relating to non-literal infringements originate from mechanical patents. While the *Custodiol I* and *Custodiol II* cases concern a pharmaceutical patent and a supplementary protection certificate, the crucial feature of these cases was a certain measurement in the claims. Disputes about construction of biotechnology patents have rarely reached the courts in Germany. However, it seems clear that the German courts will apply the equivalent test as described above to disputes about infringements of biotechnology patents.

Of particular interest in this context could also be the absolute protection of chemical compounds that has been recognized in Germany since the *Imidazuline* decision (BGH, GRUR 1972, 541). Unless the German legislators take a different view in the context of the implementation of the biotechnology directive in Germany (which is still an open issue), gene sequences could be granted protection as product patents. The real issue in such cases is not the question of defining the scope of protection of such a patent, but whether an application for such a patent fulfils the requirements of patentability. In this context, the interesting debate moves from the possibility of non-literal infringement to whether an application is inventive, and particularly whether a compound (gene sequence) shows surprising effects and characteristics that justify product protection.

The Netherlands

In the Netherlands, the Supreme Court has rendered three landmark decisions in the last two decades (*Meyn/Stork* [1989], *Ciba-Geigy/Oté Optics* [1995] and *Van Bentum/Kool* [2002]), in which the "essence of the invention" plays a central role in assessing the scope of protection of patents, without clearly distinguishing literal from non-literal infringement. In that respect, the Dutch Supreme Court clearly ruled in *Meyn/Stork* (NJ 1989/506) that in assessing the scope of the claims of a patent, the Court must rely upon the *essence* of the patented invention, rather than the literal wording of the claim.

In *Ciba-Geigy vs Oté Optics* (NJ 1995/391), the Supreme Court ruled that scope of protection has to be ascertained by considering four factors: (1) in interpreting the terms of the claims, the court is to determine the essence of the invention; in other words, consider the inventive concept behind the wording of the claims; (2) this interpretation then needs to be corrected to give a reasonable degree of certainty for third parties, which may sometimes justify a restricted, literal interpretation of the wording of the claims; (3) the skilled person may - with restraint - use the prosecution history file for the purpose of claim interpretation; (4) and all other circumstances of the case are to be taken into account, including the possible breakthrough nature of an invention (justifying a broader scope). When considering factors (2) and (3), poor drafting of the patent may be construed to be to the patentee's disadvantage. In subsequent decisions (including *Impro v Liko*, rendered three weeks after *Amgen*), the Supreme Court has expressly confirmed this approach. The approach certainly appears to be more in line with the EPC requirements, although there is a lingering feeling among practitioners that, underlying the approach, the Supreme Court still continues to embrace its essence of the invention approach.

In *Van Bentum/Kool* (NJ 2002/530), a clear case of non-literal infringement, the Supreme Court

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has clarified the approach in *Ciba-Geigy/Oté Optics* such that the skilled person is only to assume that the patentee has surrendered part of the protection (for example, beyond the literal wording of the claims but within the full extent of the invention) if there is "proper ground" for the skilled person to do so. Such "proper ground" can for example be found in the patent description or the prosecution history file.

Consequently, as a matter of law, non-literal variants are to be considered by the Supreme Court as an infringement whenever that variant is within the scope of the "essence of the invention", unless there is proper ground to conclude differently.

However, since the Supreme Court's approach was interpreted by some to be in contradiction to the rule of Article 69 of the EPC and its Protocol, there has been a tendency from the early 1990s for the lower courts to take a different approach, by clearly distinguishing literal infringement from non-literal infringement as is done in Germany. In assessing non-literal infringement, the courts use either the *function-way-result* test or the *insubstantial differences* test. In the first test, the Court asks the question whether the non-literal variant basically fulfils the same *function* as the patented one, by using basically similar *means*, leading to basically a similar *result*. In applying this test, due care is taken in interpreting the patent description. Alternatively, in some (bio)chemical cases, the *insubstantial differences* test is more easily applied, for example in assessing molecular variants. However, in applying either of these non-literal infringement tests, the courts do assess whether any protection beyond the literal wording of the claims goes beyond the full extent of the invention. Accordingly, the Supreme Court has ruled in a number of recent cases that the lower courts' approach (distinguishing between literal and non-literal infringement) is in line with its own rulings adopting the "essence of the invention" as described above.

Identifying invention is the crucial step

In the *Amgen* case, the UK court relied greatly upon the proper appreciation of the invention (ie the technical contribution to scientific knowledge) as being critical. The Court emphasised the importance of the claim wording, and the addressee's understanding of the patentee's intentions, in constructing the claims.

Similarly, rather than looking at the claims as a "point of departure" for analyzing infringement, the German and Dutch courts seem to be approaching infringement analyses on the basis that the claims play a central role in determining infringement.

The German and Dutch courts do however express their approaches in very different, and more complicated, terms to those used in the current (relative simplified) UK approach of "purposive construction". However, in all jurisdictions, identification of the full extent of the invention is the crucial step, and interpretation of the claim wording in context will be correspondingly broad (or narrow) as a result. Once the claimed invention is identified, assessment of infringement based on the claim wording, properly construed, will follow naturally.

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William is a specialist intellectual property solicitor, qualified in England & Wales, practising from Simmons & Simmons' London office. Since qualifying in 1994 he has advised clients on all aspects of IP protection, licensing and enforcement, with particular focus on patent matters. In recent years, he has advised and represented several major pharmaceutical companies, including Bayer and GlaxoSmithKline, in reported cases in the English High Court. His cases include those relating to novel pharmaceutical compounds, biotechnological inventions and modes of drug delivery. He is a member of Simmons & Simmons' pharmaceutical and biotechnology group, and advises clients on licensing and other commercial issues relating to patents and other areas of IP.

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Peter specializes in contentious and non-contentious IP and competition law matters, with a particular focus on patent litigation. He qualified in 1996 in Düsseldorf, and he joined Simmons & Simmons' Düsseldorf office in 2001. Since 2003, Peter has led the German IP practice. Peter has acted in several international and national patent infringement actions before the courts in Düsseldorf and Mannheim. The clients he has acted for represent various industries, in particular pharmaceuticals and medical devices. He also has advised biotech companies on IP law issues in the context of corporate transactions. He is a member of Simmons & Simmons' pharmaceutical and biotechnology group.

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