Bloomberg BNA

WORLD INTELLECTUAL PROPERTY REPORT >>>

News and analysis on IP law, regulation and policy from around the world. For the latest updates, visit www.bnai.com

International Information for International Business

Volume 26, Number 7 July 2012

Current Patent Litigation Trends: UK and Germany

By Jonathan Radcliffe (London) and Ulrich Worm (Frankfurt), Mayer Brown; e-mail: jradcliffe@mayerbrown.com; uworm@mayerbrown.com

I. Introduction

Previously in this series we have emphasised the importance of patentees crafting a carefully thought out pan-European patent litigation strategy designed to achieve their commercial objectives, and the importance of the United Kingdom and Germany (amongst other countries) in any such strategy.

Developing such a strategy inevitably involves a sophisticated understanding of the different legal systems in Europe, and how their advantages and disadvantages can be best incorporated into a bespoke strategy optimised for each patentee's particular objectives. Yet it must also involve an appreciation of the differences in the way the law is applied by the different legal systems in Europe. Opportunity may lie in these differences — whether it be to one's advantage or detriment.

There is undoubtedly a general European trend of convergence in the way countries apply patent law. This has especially been the case with the UK and German courts. There is a high level of communication and cooperation between the judges in both countries when faced with the same disputes, increasing judicial acknowledgment of each other's jurisprudence and the insights offered, and the adoption of common positions on a number of legal issues by the UK and German courts with the Technical Board of Appeal of the European Patent Office.

Yet some differences in approach still remain on a number of important patent issues despite this general trend of harmonisation. These can make all the difference between success and failure. This article considers some of the current key patent litigation trends in the UK and Germany. It also sets out in tabular form the overarching approaches taken in both countries to how patents are interpreted, given the importance this can have on the issues of infringement and validity; although broadly harmonised and based on the same basic law, there are nonetheless fine nuances in application between the countries which can lead to different results in practice.

II. UK Life Sciences Trends

(a) Interim Injunctions

The ability to obtain an interim injunction against a competitor is one of the most potent weapons in any litigant's armory. The price the patentee pays for this is the contingent liability — should the patent ultimately be held not to infringe or to be invalid — to recompense the defendant for any damage it has suffered as a result of the injunction.

The English Patents Court has considerably raised the price of this contingent liability by holding in life sciences cases that the patentee's customers can also claim the benefit of this so-called cross-undertaking in

damages.[1] The underlying rationale is that they are entitled to be compensated if it turns out that they have paid too much for the patentee's drugs during the pendency of the injunction.

The practical significance of this is that given that the principal customer in the country is the state, in the form of the National Health Service, then this can act as a significant deterrent to applying for an injunction. The sums involved may potentially be vast.

The result is that in practice the courts are granting speedy trials more readily than before, and patentees are more likely to agree to trade off an interim injunction for a speedy trial. Speedy trial in this context means a process typically taking under 9 months from commencement through trial and to judgment. It should also be noted that patentees are now being faced with a trade-off themselves — if they are granted an interim injunction they may also have to agree to a speedy trial as well as agree to be potentially at risk should the injunction be set aside.

(b) Medical Use and Dosage Regimes

It is trite law that the first inventor of a new product suitable for use in medical treatment is entitled to patent that product. This can cause difficulties where this is a known product and where the invention lies in the discovery of a new medical use (the so-called "first medical use") or where — although already known for medical use — the invention lies in the discovery of a new second medical use (see for example "New Uses for Old Products — SPC Applicants Get Boost From Advocate General Opinion" [26 WIPR, 7/1/12]). Such claims form an important part of the life science industry's patent portfolio.

The UK law position used to be that new ways of delivering non-novel drugs for non-novel uses could not be patented because their novelty lay in mere methods of treatment.[2] Fortunately for life sciences companies, the difficulties posed by first and second medical use patents have been addressed over the past few years, with the result that these are in principle no longer objectionable under UK law.

First medical use patents have been expressly permitted as the result of a specific enabling amendment to the Patents Act. This now provides that first medical use patents are permitted provided any medical use of the product does not form part of the state of the art, and the use is otherwise inventive.[3]

The position on second medical use patents has been resolved by the Court of Appeal decision in *Actavis UK Ltd v. Merck & Co Inc.*[4] There it was held that new dosage regimes and other methods of administration of a drug are not excluded from patentability as methods of treatment.

As a result, second medical uses are therefore permissible even if the novelty relates solely to a dosage regime or a method of drug administration. That said, the English courts' approach is nonetheless to examine such cases robustly:

- If on proper examination the invention is for a mere discovery about an old use which is dressed up as a second medical use, then it will be rejected.
- Second medical use patents will only be upheld if the active ingredient is actually effective to achieve a new treatment. If it is not, or if it is not discernibly effective, then it is not a proper second medical use, and will be rejected.

The Patents Court has recently extended the scope of second medical use patents when considering the interface between second medical use claims and enantiomers. In *Ranbaxy (UK) Ltd v. AstraZeneca AB*[5] the Patents Court held that a claim to the use of a single enantiomer of an active ingredient (omeprazole) was not infringed by the importation of a medication containing a mixture of two enantiomers, even though the manufacturing process used the single enantiomer as its raw material.

Given the importance of medical use patents to the life sciences industry, these developments are to be welcomed.

(c) Claim Interpretation and Infringement

The UK Supreme Court or House of Lords as it then was comprehensively restated the correct approach to claim interpretation and infringement in 2005 in *Kirin-Amgen v. Hoescht Marion Roussel*[6] where it held that the fundamental question was:

> "[W]hat [would] the person skilled in the art have understood the patentee to be using the language of the claim to mean?"

This approach is now being firmly applied by the UK courts in life sciences patent cases. The result is that a commonsense approach to claim interpretation is being applied by the courts that is consistent with the approach adopted towards other legal documents of any other description. The difference with interpretation of patents — and where disputes are likely to arise in the future — is in establishing the necessary context. This approach to claim interpretation requires the court to establish the knowledge and assumptions that are to be attributed to the notional addressee, namely the person skilled in the relevant art.

Recent examples of this approach as applied by the UK courts are as follows:

- *Cephalon Inc v. Orchid Europe Ltd*[7] was a dispute on infringement of the drug modafinil for the treatment of sleep disorders such as narcolepsy. On a proper interpretation of the claim both literally and acontextually, the patent claimed the particular particle size within the dosage form.

  This notwithstanding, by applying the approach mandated by *Kirin-Amgen*, the Patents Court held that the patents were intended to be practical documents addressed to technical people in industry. The court was therefore in no doubt that to such an addressee the term "composition comprising modafinil particles, wherein at least about 95% have a diameter of less than about 200 micrometers" would be understood as referring to the input active ingredient before it was formulated into tablets and not as referring to the post-formulation position.

- *Convatec v. Smith & Nephew Healthcare*[8] was a dispute on a patent for a wound dressing made of discrete modified cellulose gel forming fibres blended with at least one other such fibre. The trial judge rejected the primary submissions of both parties on what this meant and substituted his own independent claim interpretation.

   ISSN 0952-7613

The Court of Appeal upheld this approach. Following *Kirin-Amgen*, the Court of Appeal held that the skilled addressee would take the view that the patentee had chosen to define its monopoly as being based on the requirement of a blend of cellulose-based gel forming fibres mixed with gel forming fibres of some other basic chemistry.

The result is that the UK courts are now taking a nuanced approach that is firmly rooted in the overarching requirement under Article 69 of the European Patent Convention that the claims themselves must determine the scope of protection.

(d) Numerical Ranges

Life sciences claims frequently delineate the scope of the monopoly they claim by using numerical ranges (e.g. "a pH value of 5 to 8"or containing "up to 45% "). The critical question is whether numerical limits are to be treated as absolute or whether there can be some deviation outside the stated range. This is especially important in practice in formulation cases where, typically, the master patent on the active ingredient may have already expired and stopping the infringer will depend on the infringement of the particular parameters chosen by the patentee to delineate what is typically its preferred pharmaceutical product.

Some important clarity has recently been given on how such ranges should be approached. The relevant range claimed in *H Lundbeck A/S v. Norpharma SpA*[9] was "heating the mixture at 120–145° C". The Patents Court held that because the claim was expressed as a whole number it covered a range up to 145.4° C, and therefore a reaction conducted at 145.5° C or above would not infringe.

The general approach is therefore to measure infringement in accordance with scientific convention in terms of the number of significant figures used to delineate the claim — the more precision used the narrower the width of the range. This approach is entirely consistent with the post-*Kirin-Amgen* approach to claim interpretation as being the way a person skilled in the art would apply their own common general scientific knowledge in deducing what range or figures are being claimed.

III. German Life Sciences Trends

(a) Interim Injunctions

A trend with particular significance for life sciences patent litigation is the heightened number of interim injunctions being granted by German infringement courts. Interim injunctions can be obtained in Germany within a matter of weeks and are often — although not necessarily — granted in *ex parte* (without notice) proceedings.

German courts have historically always been open to granting interim injunctions in trade mark or design right infringement cases, but had been conservative about granting interim injunctions in patent infringement cases because of their inherent complexity. However, in recent years, Germany has seen an increased number of interim injunctions being granted in patent cases, including in the inherently more complex life sciences field.

This process of development culminated in the 2008 *Olanzapin* decision of the Düsseldorf Higher Regional Court granting an interim injunction for a pharmaceutical patent which had previously been nullified in first instance proceedings by the Federal Patent Court in Munich. Under the German bifurcated system, the infringement courts may not decide on the validity of a patent; this is the prerogative of the Federal Patent Court in Munich and, on appeal, of the Bundesgerichtshof (Federal Court of Justice or alternatively the German Supreme Court).

In the *Olanzapin* case, the invalidation of the patent by the Federal Patent Court was appealed to the Supreme Court. This appeal in the invalidation proceedings was still pending when the Düsseldorf Higher Regional Court granted an interim injunction. The Düsseldorf court granted its interim injunction despite the first instance invalidation decision because it took the view that the Federal Patent Court had erred in its invalidation finding and that the Supreme Court would uphold the patent in suit in the pending appeal.

Although the Higher Regional Court was subsequently proven correct in this assessment because the Supreme Court did indeed uphold the patent on appeal, this decision of the Düsseldorf court was highly controversial in Germany because it had been unprecedented. It remains to be seen whether this case will serve as a precedent for other cases in which an interim injunction is sought despite severe doubts that the patent in suit will survive invalidity attacks.

This case highlights that German infringement courts are increasingly prepared to grant interim injunctions even in pharmaceutical and other complex patent litigation cases in which the courts had historically been more reluctant to grant interim injunctions.

(b) Patentability of Dosage Regimes

Following the 1983 Federal Court of Justice decision in *Hydropyridin* the position in Germany has been that Swiss type claims on an already known active pharmaceutical ingredient are patentable. A so-called Swiss type claim covers the use of an already known active pharmaceutical ingredient for the treatment of a disease which had not previously been treated with this ingredient.

Such Swiss type claims are generally regarded as patentable subject matter which do not fall under the therapeutic use exclusions in EPC Article 52(4) and section 5(2) of the German Patent Act. According to the Federal Patent Court in its *Knochenzellenprparat* decision, patentability would even be given if a claim for a known active ingredient for a known indication would be directed towards a novel dosage regime.

The German Supreme Court in its *Carvedilol II* decision in 2007 had, however, held that mere dosage regimes for a known active ingredient for a known indication would amount to a therapeutic instruction, and hence fall under the therapeutic use exclusions. The position in Germany is therefore that mere dosage regimes for a known ingredient and a known indication remain an unpatentable subject matter.

(c) Speeding Up the Litigation Process

The German patent courts operate on a dualistic system that bifurcates infringement and validity into separate proceedings in different courts. The German infringement courts have always been among the quickest in Europe in the field of life sciences litigation (as well as in other technology areas). The planned establishment of additional patent infringement chambers and senates as

described below will help to further reduce the average length of infringement proceedings.

The introduction in 2009 of new procedural rules to streamline and accelerate patent invalidity actions should help to speed up validity proceedings, in particular at the appeal level:

- The rules require the Federal Patent Court to give detailed and meaningful guidance to the parties early on in invalidation proceedings and provide for the preclusion of belated arguments (i.e. arguments that are brought after the expiration of any deadline set by the court). Once excluded an argument will stay precluded even on appeal.

- Important changes have been made to the basis on which appeals can be made in invalidation actions. The Supreme Court hearing appeals in invalidation actions may only deal with appeals on matters of law, not on matters of fact. This will remove the need for expert witnesses at the appeal stage and help to speed up appeals in invalidation proceedings.

Despite these measures, the average length of invalidity actions in Germany (both at appeal and at first instance level) remains longer than the average length of German infringement actions. This can therefore result in a situation where an injunction may be in place for a considerable period before an appeal in the validity case finally rules the patent invalid. This position of strength can have profound consequences for settlement discussions and means that Germany will stay an attractive forum for patentees seeking to enforce their patent rights in Europe.

(d) Establishment of Additional Chambers

Germany is already widely perceived to be among the most attractive patent litigation forums in Europe — the Düsseldorf District Court (the leading infringement court in Germany) is probably the busiest in Europe. There are a number of planned major new developments which promise to make patent litigation in Germany even more attractive.

The possible advent of the Community Patent and the European Patent Litigation Agreement (EPLA) sees increased competition among the leading German patent infringement courts (the District Courts in Düsseldorf, Mannheim, Hamburg and Munich) to be the first choice for the establishment of the German national court of first instance (or courts, if Germany designates more than one) under the EPLA (and potentially also for the common Community appeal court). Thus the Düsseldorf District Court is about to establish a third patent infringement court and is contemplating establishing a second senate at the appeal level. Meanwhile, Hamburg has recently established a second patent chamber, and Munich has adopted new procedural rules aiming to speed up patent infringement litigation cases.

Each of these initiatives should have a positive effect on the duration of patent litigation in Germany, bringing the average length of patent infringement cases in those district courts closer to the benchmark set by the Mannheim District Court of 9–12 months to judgment, while maintaining the internationally regarded high quality of jurisdiction through specialised judges. These developments will undoubtedly benefit any patent litigation before these courts but will in particular have significance for life sciences patent litigation given that in the pharmaceutical, biologics and medical devices patent litigation tends to be particularly complex and protracted.

Claim Interpretation and Infringement in the UK and Germany

Overview	Deciding what exactly a patent claim means is often the single most significant issue in patent litigation. Once determined, the issue of whether there is infringement flows from this, as does the issue of invalidity (for example whether particular prior art anticipates the claim, making it invalid). The function of a patent claim is to set clear limits upon the monopoly conferred by the patent. A patent claim is intended to define clearly and with precision the monopoly claimed. This balances the interests of the public, who need to know the exact boundaries of the area within which they could be trespassers, with the interests of the patentee, who needs to be able to make it clear that no claim is made to prior art or insufficiently enabled products or processes which would invalidate the patent. Broadly, subject to certain important specific rules applicable to patents, the general approach is that patents are interpreted like other documents and the normal rules applied, for example, to contracts, will apply equally to patents. These specific patent rules have been established at a pan-European level by the EPC, which aims at creating a certain level of consistency and uniformity of approach across Europe despite the fact that claim construction remains a question of national law. Countries also have their own specific rules on patent interpretation. In some instances — UK for example — these will be the subject of detailed jurisprudence to ensure conformity of the approach to patents with that to other legal documents. Whereas German law has different interpretation rules on legal acts which require receipt by the other party (such as an offer and acceptance aimed at establishing a contract) and other legal acts which do not require receipt.
Europe (EPC)	The European Patent Convention deals expressly with the extent of protection conferred by a patent in some detail. EPC Art. 84 specifies the role of the claims in an application to the EPO for a European patent: *''The claims shall define the matter for which protection is sought. They shall be clear and concise and be supported by the description.''* Perhaps the most important provision is EPC Art. 69, which applies to infringement proceedings in the domestic courts of all contracting states. This 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.''*

   ISSN 0952-7613

Claim Interpretation and Infringement in the UK and Germany – Continued

	The interpretation of Art. 69 is set out in more detail in a protocol (see below). The effect of this has sometimes been misunderstood. It is important to note that this protocol is a protocol on the interpretation of Art. 69, not a protocol on the interpretation of claims. The Protocol to Art. 69 is as follows: *''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.''* Whilst both the UK and the German courts have their own guidelines for dealing with claim interpretation and infringement, both approach these issues with a view to answering the same ultimate question that is raised by Art. 69, namely what a person skilled in the art would have thought the patentee was using the language of the claim to mean.
United Kingdom	Both Art. 69 and the Protocol are given effect in UK law, in relation to infringement, by ss 60 and 125 of the Patents Act 1977. Section 60 provides that a person infringes a patent if he does various things in the UK ''in relation to the invention'' without the consent of the patentee. Section 125 defines the extent of ''the invention'' as follows: *''(1) For the purpose of this Act an invention for a patent for which an application has been made or for which a patent has been granted shall, unless the context otherwise requires, be taken to be that specified in a claim of the specification of the application or patent, as the case may be, as interpreted by the description and any drawings contained in that specification, and the extent of the protection conferred by a patent or application for a patent shall be determined accordingly.* *...* *(3) The Protocol on the Interpretation of Article 69 of the European Patent Convention (which Article contains a provision corresponding to subsection (1) above) shall, as for the time being in force, apply for the purposes of subsection (1) above as it applies for the purposes of that Article.''* In *Virgin Atlantic v. Premium Airways* (2009), the Court of Appeal held that the court's role was to determine what the person skilled in the art would have understood the patentee to have been using the language of the claim to mean. The applicable principles are as follows: ■ The first overarching principle is that contained in EPC Art. 69. ■ Article 69 says that the extent of protection is determined by the claims. It goes on to say that the description and drawings shall be used to interpret the claims. In short the claims are to be construed in context. ■ It follows that the claims are to be construed purposively — the inventor's purpose being ascertained from the description and drawings. ■ It further follows that the claims must not be construed as if they stood alone — the drawings and description only being used to resolve any ambiguity. Purpose is vital to the construction of claims. ■ When ascertaining the inventor's purpose, it must be remembered that he may have several purposes depending on the level of generality of his invention. Typically, for instance, an inventor may have one, generally more than one, specific embodiment as well as a generalised concept. But there is no presumption that the patentee necessarily intended the widest possible meaning consistent with his purpose be given to the words that he used: purpose and meaning are different. ■ Thus purpose is not the be all and end all. One is still at the end of the day concerned with the meaning of the language used. Hence the other extreme of the Protocol — a mere guideline — is also ruled out by Article 69 itself. It is the terms of the claims which delineate the patentee's territory. ■ It follows that if the patentee has included what is obviously a deliberate limitation in his claims, it must have a meaning. One cannot disregard obviously intentional elements. ■ It also follows that where a patentee has used a word or phrase which, acontextually, might have a particular meaning (narrow or wide) it does not necessarily have that meaning in context. ■ It further follows that there is no general ''doctrine of equivalents''. ■ On the other hand purposive construction can lead to the conclusion that a technically trivial or minor difference between an element of a claim and the corresponding element of the alleged infringement nonetheless falls within the meaning of the element when read purposively. This is not because there is a doctrine of equivalents: it is because that is the fair way to read the claim in context. ■ Finally purposive construction leads one to avoid the kind of meticulous verbal analysis which lawyers are too often tempted by their training to indulge.
Germany	The interpretation of claims of a German patent is governed by § 14 of the German Patent Act: *''The scope of protection of a patent and a patent application is determined by the patent claims. The description and the drawings, however, are to be taken into account when interpreting the patent claims.''* In the *Batteriekastenschnur* case the German Supreme Court further explained its approach as follows: *''[T]he decisive basis for establishing the scope of protection of a patent is, pursuant to § 14 of the 1981 Patent Act, the content of the claims, for the interpretation of which the description and drawings must be referred to.''* The interpretation of claims of German validations of European patents is governed by Art. 69 EPC (see above). The Supreme Court has considered the approach to claim construction under the Protocol on Art. 69 on several occasions. For example, it has held that:

Claim Interpretation and Infringement in the UK and Germany – Continued

	''In examining the question whether the patented invention is being used, it is therefore necessary to begin by establishing the content of the patent claims based on technical expertise, i.e. by determining the meaning which the person skilled in the art ascribes to the wording of the claims. If the so-determined meaning of the content of the patent claim is utilised in the challenged embodiment, then the protected invention is being used. Use of the invention may also exist in cases where the embodiment to be judged deviates from the meaning of the content of the patent claims, but where the person skilled in the art, based on ideas deriving from the meaning of the content of the invention defined in the claims, was able, due to his technical expertise, to identify the modified means employed in the challenged embodiments as being equally effective in the solution of the problem underlying the invention.'' In the famous *Formstein* case (1991) the Supreme Court held as follows: *''In determining the extent of protection of patents ... the basic question is whether the person of normal skill in the art could, on the basis of his specialist knowledge, discover the methods used in the alleged infringement, which achieve the same effect, from the claims and using the specification and drawings — and not whether the 'principle' is the same.''* Probably the most notable difference in claim construction principles between UK and Germany is that German courts apply a doctrine of equivalents whereas UK courts do not. The German Supreme Court established that the test for the doctrine of equivalents (*Schneidmesser I* (2002) and related decisions) should be determined under the following 3-step test. If the answer to all three questions is ''yes'' then there will be infringement under the doctrine of equivalents. ■ Does the alleged infringement solve the technical problem addressed by the patent through modified means yet have the same technical effect? ■ If so, could the person skilled in the art have discovered the variant forming the alleged infringement without using inventive effort (i.e. just using general knowledge and skills)? ■ If so, are these considerations of the person skilled in the art directed to the meaning of the patent claim in such a way that the person skilled in the art would consider the alleged infringement to be a technical solution equal to something that fell literally within the patent claim? At first sight, the fact that German courts recognize the doctrine of equivalents while UK courts do not might seem like a major difference in the approach to claim construction. However, embodiments found to be infringing by German courts under the doctrine of equivalents are often also considered by UK courts to be (literally) infringing under their purposive construction approach. In other words, the practical results of the different claim construction approaches between German and UK courts are often much smaller than the difference in the dogmatic approaches suggests.

Notes

[1] See *Wake Forest University Health Sciences v. Smith & Nephew plc* [2009] EWHC 45.

[2] See section 4(2) of the Patents Act 1977 and the Court of Appeal in *Bristol Myers Squibb Co v. Baker Norton Pharmaceuticals Inc* [2001] RPC 1.

[3] See section 4A(3) of the Patents Act 1977 (as amended).

[4] *Actavis UK Ltd v. Merck & Co Inc* [2008] RPC 26, Court of Appeal.

[5] *Ranbaxy (UK) Ltd v. AstraZeneca AB* [2011] EWHC 1831.

[6] *Kirin-Amgen v. Hoescht Marion Roussel* [2005] RPC 9, House of Lords.

[7] *Cephalon Inc v. Orchid Europe Ltd* [2011] EWHC 1591.

[8] *Convatec v. Smith & Nephew Healthcare* [2012] EWCA Civ 520.

[9] *H Lundbeck A/S v. Norpharma SpA* [2011] EWHC 907.

   ISSN 0952-7613