

Patents Update

May 2009

A periodical review on developments in European and Asian patent law & practice

Over the past year, Bird & Bird has increased its international footprint across Europe and Asia from 14 to 21 offices. We have also strengthened our IP litigation capabilities in several of our existing offices.

In May 2008 we became only the second international firm to enter the Finnish market with our merger with Fennica Attorneys Ltd. Our Scandinavian IP capabilities were further bolstered with the arrival of a specialist IP team from the Gozzo law firm in Sweden. The arrival of the team from Gozzo and also of Ella Mikkola in Finland makes our IP litigation and strategic advice offering one of the strongest in the Nordic region.

We have also committed ourselves to Central Europe. Following the appointment last spring of leading TMT lawyer Stephen Kines, we subsequently opened four new offices in Slovakia, Hungary, Poland and Czech Republic in September 2008.

Our expansion has not been confined to Europe; our Asian offices have also undergone a period of rapid growth over the past 12 months. Bird & Bird now has ten partners handling IP litigation in Asia. Building on our existing offices in Hong Kong and Beijing, we have recently opened our third Chinese office in Shanghai. On 1 January 2009, we entered into a global association agreement with one of Singapore's leading law firms, Alban Tay Mahtani & de Silva LLP (ATMD). The Singapore office is now known as ATMD Bird & Bird LLP. ATMD Bird & Bird has a leading reputation in a number of Bird & Bird's core sectors and practice areas and is in the top tier of IP firms in Singapore, according to the Asia Pacific Legal 500.

In April this year, we received four awards at the Managing IP Global Awards ceremony in London. These were the "European Patent Firm of the year", "German Contentious IP Firm of the year", "Spanish Contentious IP Firm of the year" and "Singapore IP firm of the year".

Contents

China: The new Chinese Patent Law	2
England: Patent decisions on patents for chiral compounds	3
England: Declaratory relief – a flexible remedy	7
England: Stays pending outcome of EPO Opposition	9
England: Patent litigation statistics	12
Europe: The current proposals for a European Patent Court	18
France: Implementation of the Enforcement Directive	20
Germany: Patent infringing offer without delivery capacity and literal patent infringement – Higher Regional Court of Düsseldorf decision in "occlusion means"	22
Italy: Preliminary injunctions in pharmaceutical patent actions	23
The Netherlands: EP 2000 improves patentee position	24
Spain: Preliminary injunctions in patent actions - recent judicial decisions	25
Contacts	28



China: The new Chinese Patent Law

Sweeping changes to the Chinese Patent Law (CPL) will come into effect on 1 October 2009. Accompanying the new CPL will be new implementing regulations and revised patent examination guidelines, although the final form of these accompanying regulations are as yet undecided. This article summarises some of the important changes.

Absolute novelty

The biggest change under the new CPL is the move to an absolute novelty regime. Under the current law, prior public uses outside China or other non-publication forms of prior disclosure outside China do not count against the novelty of a Chinese patent. Under the new CPL, public disclosure anywhere in the world prior to the filing (or priority) date will count against the novelty of a Chinese patent.

As absolute novelty is already the standard for patentability in most of the major patent filing countries, this is not likely to have an impact on applicants who are therefore used to such a practice. However, applicants from jurisdictions having relative novelty provisions or grace periods (e.g., the US) may need to reconsider their filing practice in China.

The change to an absolute novelty regime may also have a far-reaching effect on the decision whether to initiate invalidation proceedings against a Chinese patent. Chinese patents will in future be

vulnerable to an attack based on a prior use outside China. As is always the case with a prior use, however, the person relying on it will need to provide convincing evidence that the relevant information was made available to the public.

First filing / secrecy examination

At present, Chinese entities are required to file first in China for inventions completed/made in China. The new CPL removes the first filing requirement and instead introduces a new requirement that all patent applications for inventions completed/made in China filed by both Chinese and foreign entities have to undergo a secrecy examination before a foreign filing can occur. This requirement applies to any invention that is "completed in China", though at present it is unclear what exactly is meant by this term. It is thought that "completed in China" covers inventions made in China by joint Chinese and non-Chinese co-inventors.

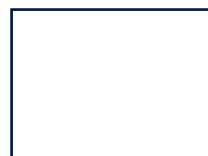
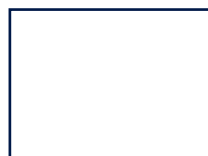
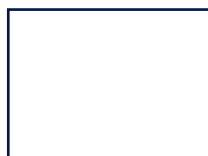
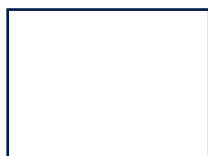
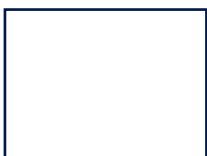
The first draft of implementing regulations which was released on 9 March 2009 classifies the criteria and time requirements. The new secrecy examination may prove to be no more burdensome than the first filing requirements already in place in many jurisdictions, or it could lead to impractical delays. As the penalty for non-compliance is severe – refusal to grant a patent or the potential loss of a granted patent – this could force applicants to first-file in China by default for all inventions completed in China.

Increase in statutory damages award

The new CPL doubles the current maximum damages statutory award to RMB1m (approx £100,000) in patent infringement cases where damages or an account of profits cannot be accurately assessed. Patentees will also be able to recover reasonable expenses under the new CPL, although Chinese courts have in the past been reluctant to allow large claims for costs and this practice is unlikely to change.

Introduction of a "Bolar" type exemption

The introduction of "Bolar" type exemptions in the new CPL will allow parties to use patented inventions to generate data for the purpose of obtaining regulatory approval prior to expiry of a patent without the patentee's licence. This change mirrors the general trend in developed nations, and the exempted acts include the making, use and importation of patented drugs or patented medical equipment and the specific making and importing of patented drugs or medical equipment solely for the purposes of obtaining and providing information required for regulatory approval. The new "Bolar" type exemption applies not only to regulatory approval for a generic drug, but also to regulatory approval for a new drug. Additionally, it is important to note that China does not have any form of patent term restoration, or supplementary protection certificate to extend the term of a patent due to delays in seeking



regulatory approval, and this has not changed under the new CPL

Explicit allowance of parallel imports

Under the current law, there is specific provision for patent exhaustion for licensed products sold in China, but no explicit guidance on products imported into China. The new CPL confirms that parallel importation into China will not be considered an act of infringement provided the patented products, or products made from a patented method, have been sold by the patent rights holder or authorised for sale by the patent rights holder. However, the new CPL does not make clear how exhaustion will apply to imported products sold outside China under contractual restrictions that limit their importation into China.

Statutory availability of pre-action injunction and evidence preservation orders

Under the current law, both pre-action injunctions and evidence preservation orders are available as a result of Judge-made law. Under the new CPL, the existing practices will be codified in statute, although obtaining a pre-action injunction in China is likely to remain difficult.

Conclusion

The amendments to the CPL coming into effect on 1 October 2009 will require legal practitioners and applicants alike to adjust their approach to Chinese patents. The change to an absolute novelty regime means that the increase in available prior

art may now make patents that were previously considered safe at risk of attack. Similarly, patentees may wish to reconsider asserting patents which were previously considered not worth asserting following the increase in the statutory damages award available.

Some other effects are harder to predict. The regulations concerning the new secrecy examination will affect everyone contemplating/conducting research and development activities in China and the full impact of this is as yet unknown. There is also hidden in this new requirement the prospect of conflict with other national laws on first filing requirements and clients are advised to tread carefully in this area.

Alison Wong and Ted Chwu, Hong Kong

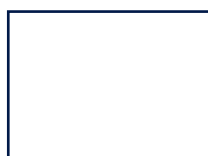
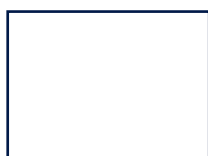
England: Patent decisions on patents for chiral compounds

A chiral compound is one which has at least one asymmetric carbon centre. As a result, there are at least two forms of the compound called enantiomers or stereoisomers. Different enantiomers normally have different functions and activities in the human body. The importance of chirality in the pharmaceutical field came to the foreground following the experience with thalidomide. Thalidomide was marketed in 1960s as a mild sedative and anti-emetic. Thalidomide is chiral and has two

enantiomers one of which was a non-teratogenic sedative and the other of which was teratogenic. As a result of being taken by pregnant women, thalidomide caused widespread deformities in the children of those women. As an aside, thalidomide is atypical in that each of the two enantiomers reverts over time to a mixture of the two enantiomers i.e., they self-racemise. Thalidomide has been found to be useful for treating other diseases but is of course now contraindicated for various classes of patients including pregnant women.

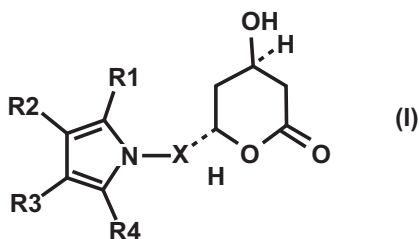
The first patented chiral compound to be litigated fully in the English courts was atorvastatin in the mid-1990s (Ranbaxy v Warner-Lambert). The Patents Court decision was handed down in October 1995 and the Court of Appeal decision in June 2006. This case has been followed in the past couple of years by two further cases, the first concerning escitalopram (Generics v Lundbeck) and the second concerning levofloxacin (Generics v Daiichi). The Patents Court decision in the levofloxacin case was handed down last year and the House of Lords decision in the escitalopram case was handed down in January of this year.

In this article, we consider the issues raised in these cases arising out of the chiral nature of the compounds the subject of the patents in suit. The decision on the sufficiency issue argued in the House of Lords in the escitalopram case, however, is applicable to all patents and not just those concerning chiral compounds.



Infringement

Two patents were in dispute in the atorvastatin case. The second was held invalid for lack of novelty and obviousness at first instance and the finding of lack of novelty was upheld on appeal. The validity of the first patent (referred to as the basic patent) was not in issue. The defendant Ranbaxy however had requested a declaration of non-infringement of the basic patent. The basic patent claimed the chemical compound atorvastatin defined by reference to the structure of the compound. Thus, claim 1 was to "A compound of structural formula" (I).



Apart from the structure, the only reference in the basic patent to stereochemistry was in the following passage:

"The compounds of structural formula 1 above possess two asymmetric carbon centres, one at the 4-hydroxy position of the pyran-2-one ring and the other at the 6-position of the pyran-2-one ring where the alkylpyrrole group is attached. The asymmetry gives rise to four possible isomers, two of which are the R-cis- and S-cis- isomers and the other two of which are the R-trans- and the S-trans-isomers. This invention contemplates only the trans- form of the compounds of formula 1 above."

Ranbaxy wished to sell the therapeutically active enantiomer and argued that the claim covered the racemate but not each of the two trans-enantiomers separately.

At first instance, Pumfrey J, construing the claim through the eyes of the notional skilled addressee and in the context of the specification, held that the claim covered not merely the racemate but also each of the two trans-isomers separately. He therefore refused to grant the declaration. His decision was upheld on appeal to the Court of Appeal.

Pumfrey J's decision on the issue was based on his findings of fact as regards the common general knowledge of the skilled addressee at the date of the basic patent in 1986 and in particular the fact that the skilled addressee would have appreciated that (1) the compound comprised a number of enantiomers, (2) one of the enantiomers was likely to be considerably more therapeutically effective as a cholesterol lowering drug than the other (a feature of this class of drug) and (3) the racemate was resolvable into its constituent enantiomers using conventional techniques.

Novelty

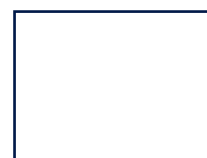
The issue which arose for the first time in the levofloxacin case was whether a claim to an enantiomer was anticipated by the prior disclosure of the racemate (as well as the way of making the racemate).

The defendant in the levofloxacin case accepted that the claim in issue did not extend to the racemate i.e., it covered only

the enantiomer. The prior art relied upon as anticipating the claim was a prior patent and a prior paper, both of which disclosed ofloxacin (the racemate) and also a way of making it.

Kitchin J held, relying on the House of Lords decision in *Synthon v SKB* (2005 UKHL 59) that the claim was not anticipated. As Lord Hoffman had made clear in the *Synthon* case "... anticipation requires prior disclosure of subject-matter which, when performed, must necessarily infringe the patented invention" Kitchin J held as a matter of fact that neither of the two pieces of prior art taught or suggested resolution of the racemate (ofloxacin) into its two constituent enantiomers (one of which was levofloxacin).

In reaching this conclusion, Kitchin J took comfort from the obiter dicta made by Lord Hoffmann in the Court of Appeal decision in the *escitalopram* case. In the *levofloxacin* case, the defendant accepted that the prior art did not anticipate the isolated enantiomer. Lord Hoffmann had commented on the fact that this approach was consistent with the settled jurisprudence of the EPO namely that the disclosure of the racemate does not in itself amount to a disclosure of the enantiomers. The point did not arise for a decision in the *escitalopram* case because the defendant had argued that the claim to the enantiomer in that case covered not merely the isolated enantiomer but also the enantiomer as part of the racemate. The anticipation attack in the *escitalopram* case therefore turned on the construction of that claim i.e., whether it included the



enantiomer as part of the racemate. Kitchin J held that it did not and his decision on this issue was upheld by the Court of Appeal.

As an aside, it is worth noting that in the levofloxacin case Kitchin J declined to follow several decisions of the German Patents Court which had come to a different conclusion on the same issue on the basis that they had conflated the issues of novelty and obviousness. In January of this year, in the appeal in the olanzapine case in Germany, the German Supreme Court in fact overturned one of those decisions of the German Patents Court finding that the test applied by the German Patents Court was too broad. In the light of that decision, it is expected that the German Supreme Court will also overturn the German Patents Court decision on novelty in the German escitalopram case. Overall, it seems that the German courts are moving towards the more "photographic" approach to novelty traditionally applied by the English courts.

Obviousness

Obviousness is an issue which turns on the specific finding of facts made by the Court based on the opinions of the experts giving evidence on behalf of the parties.

In the atorvastatin case, obviousness was an issue as regards the second patent which was directed to the hemicalcium salt of the therapeutically active enantiomer of atorvastatin. At first instance, Pumfrey J held that the second patent was invalid for both anticipation (over an intervening

reference) and obviousness (over the basic patent). As the anticipation attack was upheld on appeal, the Court of Appeal did not hear argument on the issue of obviousness.

In the levofloxacin case, Kitchin J held that the patent was not invalid for obviousness. The obviousness attack was based on common general knowledge alone as well as three papers emanating from Riker. As regards common general knowledge alone, Kitchin J held that as at 1985 the priority date of the levofloxacin patent (1) the notional skilled addressee would have considered investigating whether the enantiomers of ofloxacin could be separated fairly easily but if they could not then he would have redirected his efforts elsewhere and (2) the enantiomers could not be separated easily – resolution would have involved a research programme of uncertain outcome. Accordingly, he held the patented invention of levofloxacin not obvious over common general knowledge alone. As regards the three papers emanating from Riker, he held that the disclosures in each of them would not have made the resolution of the enantiomers any easier and therefore that the claim to levofloxacin was not obvious over any of them together with common general knowledge.

Finally, in the escitalopram case, Kitchin J held that the patent was not invalid for obviousness. The obviousness attack was based on two prior published patents both of which disclosed the racemate and methods to make the racemate but did not disclose either the enantiomers nor the

means of making them i.e., the means of resolving the racemate.

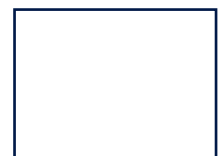
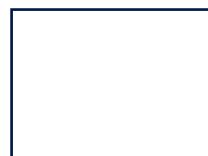
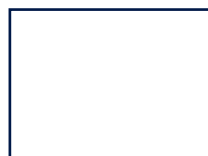
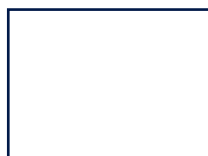
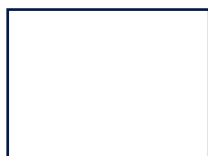
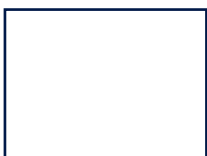
Kitchin J held that whilst the skilled addressee would have had an incentive in 1988 to resolve the racemate, it would not have been a straightforward exercise – resolution would again have involved a research programme of uncertain outcome.

In both the levofloxacin and escitalopram cases, the same Judge at first instance had to consider whether the patentee was entitled to rely on the unexpected benefits of the invention in support of non-obviousness. In the escitalopram case, Kitchin J held that unless the unexpected benefits were disclosed or at least foreshadowed in the specification then the patentee was not entitled to rely upon them. In the levofloxacin case, the unexpected benefit was described in the specification as filed but not in the priority document. He upheld the patentee's claim to priority but held that the patentee was not then entitled to rely on a discovery made after the priority date and not described or foreshadowed in the priority document.

As a further aside, it is interesting to note that earlier this year, the District Court of The Hague held that the Dutch part of the escitalopram patent was invalid on the ground of obviousness.

Sufficiency

In the escitalopram case, claims 1, 3 and 6 of the patent were in issue. Claim 1 was directed to the enantiomer itself (escitalopram), claim 3 was directed to the



pharmaceutical composition containing escitalopram and claim 6 was directed to the process of making escitalopram.

Kitchin J decided at first instance that claims 1, 3 and 6 were novel and non-obvious. However, he held claims 1 and 3 invalid for insufficiency on the basis that they covered escitalopram howsoever made and yet the patent itself disclosed only two ways of making it. Relying on the House of Lords decision in *Biogen v Medeva*, he held that because it was obvious to try to make escitalopram but the difficulty lay in doing so, the technical contribution made by the patent only extended to escitalopram made using the (two) methods disclosed in the patent and therefore the monopoly conferred by the patent should be confined to that invention.

The Court of Appeal upheld Kitchin J's findings on novelty and non-obviousness but reversed his finding on insufficiency. Interestingly, Lord Hoffmann who normally sits in the House of Lords, came down from the Lords to sit on the Court of Appeal panel hearing the appeal. The crucial distinction drawn by Lord Hoffmann was that the claims in issue in *Biogen* were "product by process" claims whereas those in the escitalopram case were mere "product" claims. He went on to point out that the Judge had wrongly equated the "technical contribution" with the "inventive step". He considered that the invention in the escitalopram case was the way of making the enantiomer whereas the technical contribution was the enantiomer itself.

It is of interest that in a separate Judgment, Jacob LJ qualified to some extent what Lord Hoffmann had said in order to show that a claim covering more than one product could in certain circumstances still be vulnerable to an insufficiency attack.

"So, for example, if a man finds a particular way of making a new substance which is 10 times harder than diamond, he cannot just claim "a substance which is ten times harder than diamond." He can claim his particular method and he can claim the actual new substance produced by his method, either by specifying its composition and structure or, if that cannot be done, by reference to the method ... but no more. The reason he cannot claim more is that he had not enabled more – he has claimed the entire class of products which have the known desirable properties yet he had only enabled one member of that class. Such a case is to be contrasted with the present where the desirable end of indeed fully enabled – that which makes it desirable forms no part of the claim limitation."

Of even more interest given that Lord Hoffmann had himself been a member of the tripartite panel of the Court of Appeal hearing the appeal, the House of Lords gave permission to the defendants to petition against the decision of the Court of Appeal. The House of Lords decision was handed down in late February.

The House of Lords in effect rubber-stamped Lord Hoffmann's Court of Appeal

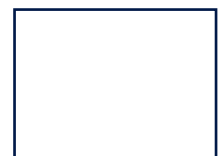
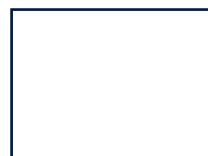
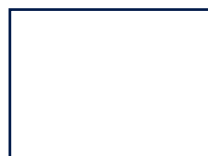
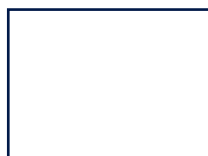
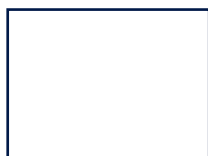
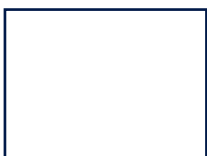
decision – in relation to a simple product claim i.e., a claim to a new product (not defined by reference to the way in which it is made), the claim is enabled provided that the patentee discloses one way of making it. The claim is not therefore invalid for insufficiency even if there are other ways of making the product that owe nothing to the technical contribution to the art made by the patentee (i.e., the one way of making it) which is disclosed in the patent.

Validity of SPCs for enantiomers

In the levofloxacin case, the validity of the SPC for levofloxacin was attacked on the basis that the relevant marketing authorisation was not that for levofloxacin itself but rather the earlier marketing authorisation for the racemate ofloxacin.

Kitchin J distinguished the ECJ decisions in *BASF* which concerned the products differing only in respect of their impurity levels and the *MIT* case which concerned the combination of an active and non-active excipient. On the basis that the ofloxacin (the racemate) and both enantiomers were in effect different drugs having different therapeutic effects, he held that the relevant marketing authorisation was not that for ofloxacin but rather the one on which the SPC had been based namely that for levofloxacin.

Neil Jenkins, London



England: Declaratory relief – a flexible remedy

Recently the English courts have shown a willingness to grant new kinds of declarations in patent cases where a declaration of non-infringement was not an appropriate remedy. This article looks at these and other developments of the English courts' declaratory relief jurisdiction.

Background – English law

The current basis for the grant of declaratory relief is CPR Part 40.20, which states that: "The court may make binding declarations whether or not any other remedy is claimed."

The limits on this jurisdiction have generally been set by case law. One limit is that the court will not answer hypothetical questions. If the declaration would serve no useful purpose - graphically described by Pumfrey LJ in his last judgment, *Nokia Corporation v InterDigital Technology Corporation* [2007] EWHC 3077 (Pat), as "the legal equivalent of shouting in an empty room" - the court will not entertain such a claim.

For a long time the received wisdom from the cases was that the courts would not grant negative declarations unless they were specifically authorised by statute, such as declarations of non-infringement of a patent (Patents Act 1977 section 71). However, in recent years this has changed.

In 2000 the Court of Appeal made it clear that the court had jurisdiction to grant declarations, both positive and negative, even when no other claim had been made. The issue was one of discretion, not jurisdiction.

In the area of patent litigation, two new types of declaration have recently been granted, a declaration of non-essentiality and a declaration that the applicant's product was obvious.

Declaration of non-essentiality

The ability of a court to grant a declaration that specified patents are not essential to the practice of a standard has been clearly established by the Court of Appeal in two cases involving mobile telecommunications.

Background

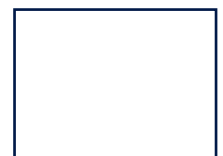
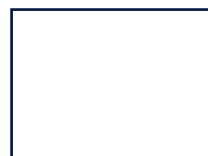
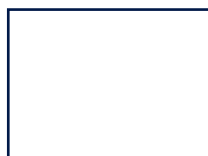
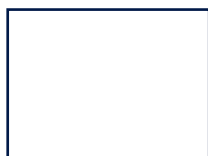
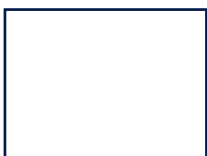
As all devices used in mobile telecommunications systems have to work together, regardless of manufacturer, standards are essential. Standards are developed by bodies in which the participants in the industry collaborate in developing and agreeing technical standards. However, if a standard is adopted, anyone having a patent essential to the practice of that standard could be in a position to put competing manufacturers out of business or at least to demand very high royalties for a licence. To deal with this problem, the standard setting bodies have adopted IP policies, which generally require participants in the standard setting procedure to declare IP rights which they hold which are, or could become, essential

to the practice of that standard and to agree to licence those rights under fair, reasonable and non-discriminatory (FRAND) terms. The European standards body for telecommunications, ETSI, has adopted such a policy and very large numbers of patents have been notified to it by their owners as 'essential', as defined by the ETSI policy. ETSI makes no checks as to whether or not these patents are truly essential.

Nokia v Interdigital I

Nokia is the largest manufacturer of mobile phone handsets. InterDigital is a US company which owns a large number of patents relating to mobile telecommunications but which no longer manufactures equipment. Its source of income is now mainly from licensing.

The dispute arose between the parties over a claim by InterDigital to an increased royalty rate in an existing licence to Nokia, which Nokia disputed. Extensive international litigation between the parties ensued. In the UK Nokia brought an action for revocation of four InterDigital patents which had been declared to ETSI as essential to the GSM standard. Nokia did not seek a declaration of non-infringement because the parties agreed that all the patents were included in the existing licence, which neither party wished to terminate. After the action commenced, Nokia applied to amend the complaint to add a claim for a declaration that the patents were not essential to the ETSI GSM standard, which was resisted by InterDigital.



Pumfrey J allowed the amendment and InterDigital appealed. The Court of Appeal upheld the judgment, holding that the meaning of 'essential' was clear and there was a real commercial issue between the parties in relation to essentiality, despite the licence, so the court could exercise its inherent jurisdiction to grant such a declaration if after trial this was justified: [2005] EWCA (Civ) 614.

Nokia v Interdigital II

In a subsequent action, Nokia sought declarations that 30 of InterDigital's patents were not essential to the 3G mobile phone standards. Nokia no longer had a licence from InterDigital, so if the patents were truly essential Nokia would need one. InterDigital tried to strike out these claims, which was refused by Pumfrey J. On appeal, the Court of Appeal held that the court had jurisdiction to grant such a declaration where there was a real reason for doing so. Here Nokia had a real commercial interest in knowing where it stood in relation to needing a licence for these patents. A declaration of non-infringement would not be an adequate substitute, as Nokia would have to seek one of these each time it introduced a new 3G handset, whereas the declaration sought would cover all its 3G products: [2007] EWCA (Civ) 1618.

At trial only four patents remained in contention. In December 2007 Pumfrey LJ held that three of the four were not essential to the 3G standard, and that the apparatus claims of the fourth patent were not essential but the method claims

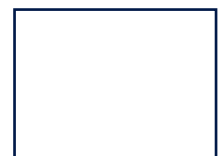
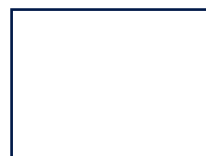
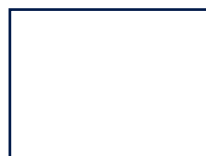
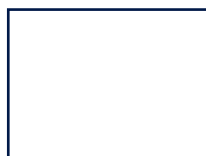
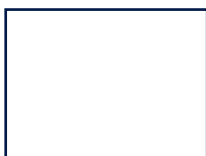
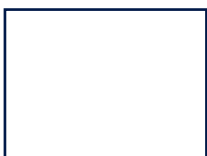
were essential. He held that declarations to this effect would have practical utility in connection with licensing negotiations, and granted them: [2007] EWHC 3077 (Pat).

European Commission – standards and intellectual property rights

The issue of patent ambush within standard setting has come to the attention of the European Commission as noted in its publication "Communication from the Commission to the European Parliament, the Council and the European Economic and Social Committee, an Industrial Property Rights Strategy for Europe" (COM(2008) 465/3). It is seen as an area of growing importance between industrial property and competition law. The Commission calls on the standard setting authorities, such as ETSI, to make effective policies to ensure disclosure and commitments to license access to essential patents on FRAND terms. The Commission will launch a fact-finding study to analyse the interplay between intellectual property rights and standards in the promotion of innovation and adopt a consultative document on standardisation in information and communications technologies in the first quarter of 2009 which will include how standards relate to industrial property rights in the sector.

Declaration of obviousness

The central importance of utility in the exercise of the court's discretion was illustrated by the decision of Kitchin J in *Arrow Generics Ltd v Merck & Co. Inc* [2007] EWHC 1900 (Pat). The product in issue was the drug alendronate, which had been first marketed in 1995. Merck applied for a European patent on a particular dosage regimen for the drug claiming a 1997 priority date. The parent patent was granted by the EPO but then held invalid by the English courts. It was also subsequently revoked by the EPO in opposition proceedings. However, during prosecution of the parent patent Merck filed four separate divisional applications. Following the revocation of the parent patent by the EPO, Merck then prosecuted the first of these divisionals through to grant by the EPO. Following the grant of the first divisional, Merck made statements indicating an intention to enforce this patent. Merck also decided to withdraw the UK designation. Before this withdrawal had been published, however, Arrow commenced proceedings in England to revoke this divisional patent and also for a declaration that its generic alendronate product would have been obvious at the 1997 priority date of all of the divisional patents. The purpose of the declaration was to remove any threat of further proceedings against Arrow on the three remaining pending divisional patent applications. Merck applied to strike out the proceedings.



The claim for revocation was struck out because having withdrawn the UK designation, the UK patent was never granted i.e., there was nothing to revoke. However, the claim for a declaration that the generic product was obvious was not struck out and therefore allowed to proceed. The possibility of other divisional patents being granted meant that a threat hung over Arrow's continued sales of its generic product in the UK. This threat could not be removed by revocation proceedings unless and until the divisional patents were granted by the EPO. Further, Merck had refused to give an assurance that it would not seek to enforce any such divisional patents against Arrow. In these circumstances, the Judge held that the declarations sought would serve a useful purpose and there was a clearly defined issue on which the court could rule. As a result, the claim for the declaration that the generic product was obvious at the priority date was allowed to proceed.

Interestingly, in parallel proceedings in the Netherlands, the District Court of The Hague actually granted a declaration in these terms i.e., that the generic product was obvious at the priority date. That decision is under appeal.

Hilary Pearson, London

England: Stays pending outcome of EPO Opposition

The Court of Appeal in England has recently set out important guidance to Judges in the Patent Court as to how they should determine whether an English action in which the validity of a patent is in issue should be stayed pending the outcome of an Opposition involving the same patent at the European Patent Office (EPO).

Historically, the English courts have been reluctant to stay national proceedings pending the outcome of an Opposition. One of the main reasons for this reluctance was the long time taken by the EPO to reach a final decision. In 2000, Neuberger J (as he then was) granted a stay in *GHC v Bracco* and in the years that followed there was a sense that the courts were becoming more willing to grant stays in some circumstances.

The recent Court of Appeal decision in *Glaxo v Genentech* has not only made it clear that timing and commercial certainty are of paramount importance in deciding whether to stay or not but also provided the first instance Judges with some practical guidelines as to how to decide such applications.

Factual background

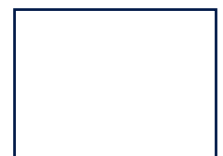
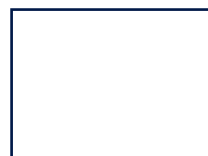
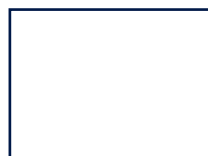
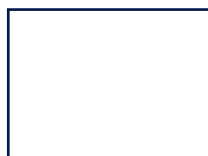
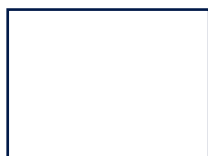
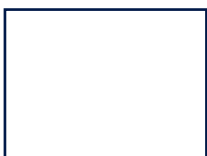
In August 2006, Glaxo commenced an opposition against a European Patent

granted by the EPO and owned by Genentech. Six months later, on 19 February 2007, Glaxo commenced a revocation action in England against the UK part of the European Patent on the same grounds as those relied upon before the EPO. Genentech made an application in the English action for an order staying the English proceedings pending the outcome of the EPO opposition. To encourage the court to grant the order for a stay, Genentech offered undertakings to the court that they would not commence an action for infringement of the European Patent (UK) against Glaxo nor its customers during the period of the stay nor claim any financial relief other than damages on a reasonable royalty basis nor seek an injunction or order for delivery up during the period of the stay and that they would prosecute the EPO proceedings using all reasonable endeavours.

First Instance decision

At first instance, the Judge refused to make an order for a stay. However, he noted that this decision was out of line with the way in which such applications would be decided in a commercial case and indicated that it would be useful for the Court of Appeal to examine the current practice of the Patents Court in relation to such applications.

Genentech appealed against the decision although at the hearing of the appeal they confirmed that they had decided to consent to revocation of the European Patent (UK). The Court of Appeal nevertheless decided that they would go



ahead and deliver their Judgment as there was a wider public interest involved in the issues raised by the appeal. Glaxo supported the Court of Appeal as they recognised that the point arose frequently in patent litigation and wanted there to be a clearer understanding of the principles. Also, both parties had already incurred substantial costs in relation to the application and they welcomed the court's recognition that the costs and efforts put into it should not be wasted.

Court of Appeal decision

The guidance the Court of Appeal laid down when the Patent Court should have the discretion to stay legal proceedings pending EPO decision was laid out in nine points as follows:

First, the discretion to order a stay, which is very wide indeed, should be exercised to achieve the balance of justice between the parties having regard to all the relevant circumstances of the particular case.

Secondly, it is the discretion of the Patents Court, not of the Court of Appeal. The Court of Appeal would not be justified in interfering with a first instance decision that accords with legal principle and has been reached by taking into account all the relevant, and only the relevant, circumstances.

Thirdly, although neither the EPC nor the 1977 Act contains express provisions relating to automatic or discretionary stay of proceedings in national courts, they provide the context and condition the exercise of the discretion.

Fourthly, the possibility of the duplication of proceedings contesting the validity of a patent granted by the EPO is inherent in the system established by the EPC. In practice, national courts exercise exclusive jurisdiction on infringement issues and they have concurrent jurisdiction with the EPO on validity issues. The Contracting States and the UK Parliament contemplated that the national Patents Courts should be able to determine the same issues of patentability as the EPO. The resultant legislation allowed the determination by the national court and the EPO to proceed at the same time. Indeed, there is nothing in the EPC or the 1977 Act to prevent the commencement of revocation proceedings in the Patents Court on the very date of the grant of the patent by the EPO.

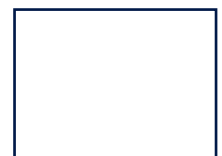
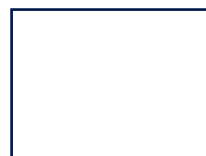
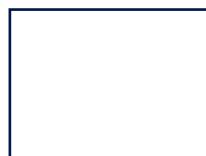
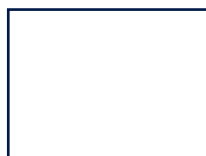
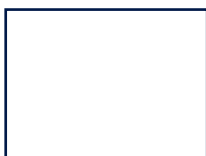
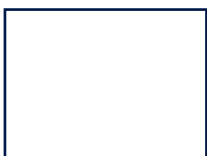
Fifthly, this setting indicates that, in present conditions, one factor affecting the discretion will usually carry more weight than any other. That is the length of time that it will take for the respective proceedings in the national court and in the EPO to achieve some certainty on the issue of the validity of the patent in suit so that business knows where it stands. The length of the stay of proceedings, if granted, is, in general, the most significant factor in the discretion. Both the parties' legitimate interests and the public interest are in dispelling the uncertainty surrounding the validity of the monopoly rights conferred by the grant of a patent and the existence or non-existence of exclusive proprietary rights on a public register. A decision in the revocation

action in the Patents Court will dispel some of the uncertainty. If the likelihood is that proceedings in the Patents Court would achieve this resolution significantly sooner than the proceedings in the EPO, it would normally be a proper exercise of discretion to decline to stay the Patents Court proceedings. They should be allowed to proceed to a decision that would supply some certainty in the public interest and the parties' legitimate interests.

Sixthly, there are no grounds justifying the application by the Patents Court of a presumption that the duplication of legal proceedings in it and in the EPO is, without more, a ground for a stay of the proceedings in the Patents Court, as the EPC system allows for parallel proceedings contesting the validity of the patent in both the international court (which is what the EPO in substance is) and in the national court.

Seventhly, the Patents Court judge is entitled to refuse a stay of the national proceedings where the evidence is that some commercial certainty would be achieved at a considerably earlier date in the case of the UK proceedings than in the EPO. It is true that it will not be possible to attain certainty everywhere until the EPO proceedings are finally resolved, but some certainty, sooner rather than later, and somewhere, such as in the UK, rather than nowhere, is, in general, preferable to continuing uncertainty everywhere.

Eighthly, much weight should be given to an assertion by a commercial party that it has a good reason for resisting a stay.



Normally a party is the best judge of its interests. Contentions of a competitor that there is no commercial need for early resolution of validity, should be viewed with suspicion. Detailed arguments of the sort advanced here are unlikely to carry weight and a judge would be justified in dealing with them shortly.

Lastly, other considerations in the particular case may affect the balance of justice, such as the additional costs in the duplication of proceedings, the order in which the proceedings were commenced and so on, but, in general, the other factors, though relevant, are of lesser importance than achieving some commercial certainty somewhere sooner. The judge will receive evidence and submissions on other relevant factors, but should be wary of over-elaboration of the issues by the parties in their evidence and legal submissions. Although due consideration must, of course, be given to the evidence and the arguments, the actual exercise of the discretion does not require the judge to deliver a judgment dealing in detail with all the points taken by the parties. A global assessment of the relevant material, supported by valid reasons, is normally sufficient to justify the decision to refuse or to grant a stay.

Finally, the Court of Appeal held that the Patent Court judge decision not to grant a stay could not be faulted and the appeal was dismissed.

As stated above, the Court of Appeal has firmly re-established that achieving commercial certainty is of paramount importance in determining whether a stay should be granted or not. Therefore, in England, in most cases a stay is unlikely to be granted because of the time taken by the EPO to reach a final decision.

Mary Smillie, London

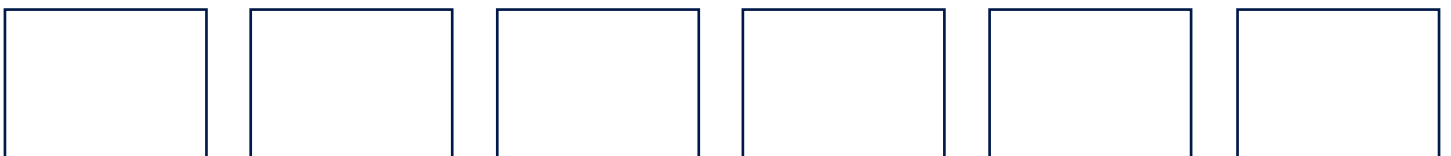
England: Patent litigation statistics

As in previous Updates, we have summarised in the tables below the outcomes of the first and second instance patent infringement and invalidity decisions for 2007 and 2008 and the first instance decisions for the first few months of 2009.

The main trends observed over this period are firstly a smaller proportion of litigated patents being found invalid for obviousness at first instance and second, a smaller proportion of litigated patents being found invalid.

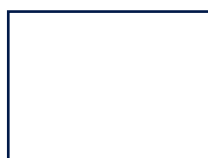
These trends are certainly consistent with the anecdotal evidence that the English courts are more inclined to maintain the validity of patents than in the past.

In December 2007, Mr Justice Pumfrey sadly died shortly before taking up his new appointment in the Court of Appeal. Mr Justice Floyd had previously been appointed as the second Patents Judge in October 2007. Finally, in October 2008, as a consequence of the number of patent actions being heard by the Patents Court, Mr Justice Arnold was appointed as a third Patents Judge.



Patents Court and Patents County Court Judgments on Validity and Infringement for 2007

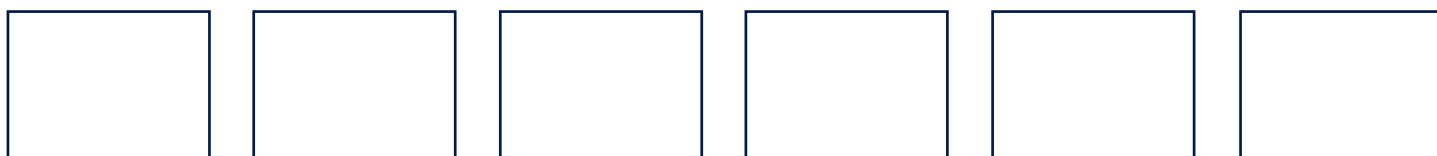
Date	Parties	Citation	Subject matter	Judge	Infringed	Valid?	Appealed?
02.03.2007	Baxter v Abbott	[2007] EWHC 348	Pharmaceutical: Sevoflurane EP 0 967 975	Pumfrey J	No	No - Insufficient. anticipated & added matter	No
.15.03.2007	LB Europe v Smurfit Bag in Box & ors	[2007] EWHC 510	Wine box tap EP 0 432 070	Wyand QC	No	Yes	Upheld - [2007] EWCA 933
26.03.2007	European Central Bank v Document Security System	[2007] EWHC 600	Anti-copying device EP 0 455 750	Kitchin J	N/A	No - Added matter	Upheld - [2008] EWCA 192
04.05.2007	Generics & Ors v H Lundbeck A/S	[2007] EWHC 1040	Pharmaceutical: Escitalopram EP 0 347 066	Kitchin J	N/A	C6: Yes CI&3: No - Insufficient	Reversed - [2008] EWCA 311
06.06.2007	Actavis v Merck	[2007] EWHC 1311	Pharmaceutical: Finasteride EP 0 724 444	Warren J	N/A	No - Anticipated	Reversed - [2008] EWCA 444
15.06.2007	Triumph Actuation Systems v Aeroquip- Vickers	[2007] EWHC 1367	Power Transfer Unit EP 0 280 532	Pumfrey J	Yes	No - Added matter	No
11.07.2007	Servier v Apotex	[2007] EWHC 1538	Pharmaceutical: Perindopril EP 1 296 947	Pumfrey J	Yes	No - Obvious & CI: Anticipated	Upheld - [2008] EWCA 445
06.09.2007	Handi-Craft & anr v B Free World & ors	[2007] EWHC B10	Baby Bottles EP 0 845 971	HHJ Fysh	Yes	No - Obvious	Upheld - [2008] EWCA 868
04.10.2007	Siemens Schweiz v Thorn Security	[2007] EWHC 2242	Coating PCB EP 0 577 094	Mann J	Yes	Yes	Reversed as to infringement - [2008] EWCA 1161
10.10.2007	Monsanto Technology v Cargill International	[2007] EWHC 2257	GM Crops EP 0 546 090	Pumfrey J	No	Yes	No
10.10.2007	University of Queensland v Siemens Magnet Technology	[2007] EWHC 2258	MRI Magnets GB 2 308 451	Pumfrey J	Yes [in part]	No - Added matter & Obvious	No
12.10.2007	Teva Pharmaceutical Industries v Merrell Pharmaceuticals	[2007] EWHC 2276	Pharmaceutical: Fexofenadine EP 0 639 976 EP 0 701 443 EP 0 815 860	Warren J	N/A	No as to the 9 claims in issue of the 3 patents in issue - 8 Anticipated, 9 Obvious	No



Date	Parties	Citation	Subject matter	Judge	Infringed	Valid?	Appealed?
14.11.2007	Wobben v Vestas-Celtic Wind Technology	[2007] EWHC 2636	Wind Turbine Technology EP 1 282 774 (invalid) EP 1 040 564 EP 1 164 691 EP 1 386 078	Kitchin J	No x 2 (564 & 691)	Abandoned x 1 (078) No x 3 564 - No, for added matter, obvious and insufficient; 691 - claim 1 as granted invalid but all proposed amendments refused as added matter and either obvious or insufficient; 078 - Accepted all except 2 claims, one proposed amendment refused as obvious but other allowed.	No
21.12.2007	Nokia v Interdigital Technology	[2007] EWHC 3077	3G Mobile Phone Technology EP 0 515 610 EP 0 855 807 EP 1 062 749	Pumfrey LJ	No x 3 Yes x 1 (as to essentiality)	N/A	No

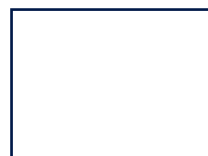
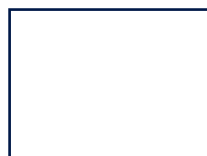
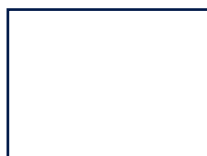
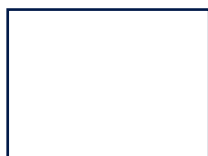
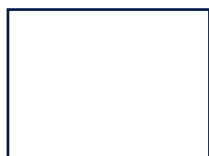
Court of Appeal Judgments on Validity and Infringement in 2007

Date	Parties	Citation	Subject matter	Judge Upheld?	Infringed	Valid?	Appealed?
16.01.2007	Conor Medsystems v Angiotech	[2007] EWCA 5	Medical Device: Drug coated stents EP 0 706 376	Yes	NA	No - Obvious	Upheld [2008] UKHL 49
02.08.2007	LB Europe v Smurfit Bag in Box & ors	[2007] EWCA 933	Wine Box Tap EP 0 432 070	Yes	No	N/A	No
18.10.2007	Novartis v Ivax	[2007] EWCA 971	Pharmaceutical: Cyclosporin UK 2 222 770 UK 2 380 674	Yes	No	N/A	No



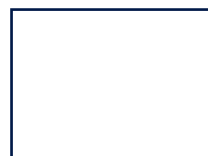
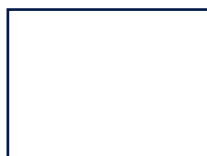
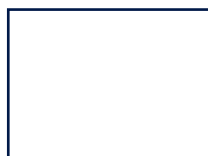
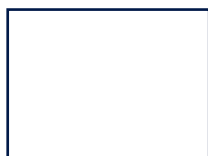
Patents Court and Patents County Court Judgments on Validity and Infringement for 2008

Date	Parties	Citation	Subject matter	Judge	Infringed	Valid?	Appealed?
07.02.2008	Qual-Chem Ltd v Corus UK Ltd	[2008] EWPC 1	Steel Making Process GB 2 363 635	HHJ Fysh	Yes	Yes	Yes - Upheld [2008] EWCA 1177
28.02.2008	Research in Motion UK Ltd v Visto Corporation	[2008] EWHC 335	Telecoms EP 0 996 905	Floyd J	Yes	No - Obvious, and computer program as such	No
03.03.2008	Qualcomm Incorporated v Nokia Corporation	[2008] EWHC 329	Telecoms EP 0 629 324 EP 0 695 482	Floyd J	Yes x 2	No x 2 - 324 Anticipated and obvious, Claims 1, 2, 9 and 11 of 482 Obvious and claims 9 and 11 of 482 insufficient	No
21.04.2008	Abbott Laboratories Ltd v Evvzio Medical Devices ULC	[2008] EWHC 800	Medical Devices: Coronary Stents EP 0 888 093 EP 0 888 094 EP 1 066 804	Kitchin J	Yes as to 093 and 084, no as to 094	No x 2 - 093 and 804 obvious Yes as to 094	No
21.04.2008	Buhler AG v FP Spomax SA	[2008] EWHC 823	Milling Process EP 0 336 939	Mann J	Admitted	No - Obvious	No
14.05.2008	Aerotel Ltd v Wavecrest Group Enterprises Ltd & ors	[2008] EWHC B4	Telecoms GB 2 171 877	HHJ Fysh	Yes	No - Obvious, and business method and computer program as such	Yes, pending 05/09
12.06.2008	Alan Nuttall Ltd v Fri-Jado UK Ltd & anr	[2008] EWHC 1311	Hot Food Display Cabinet GB 2 348 697	Prescott QC	Yes	Yes	Yes, pending 07/09
25.06.2008	Zipher Ltd v Markem Systems Ltd & anr	[2008] EWHC 1379	Tape Drives GB 2 369 602 EP 1 767 375	Floyd J	Yes x 2	No x 2 - 602 and 375 insufficient	No
30.06.2008	Actavis UK Ltd v Janssen Pharmaceutica NV	[2008] EWHC 1422	Pharmaceutical: Nebivolol EP 0 334 429	Floyd J	N/A	No - Anticipated & obvious	No
31.07.2008	Eli Lilly & Company v Human Genome Sciences, Inc	[2008] EWHC 1903	Neutrokine - α polypeptide EP 0 939 804	Kitchin J	N/A	No - Obvious, insufficient and lacking industrial applicability	Yes, pending 12/09
07.10.2008	WL Gore & Associates GmbH v Geox SpA	[2008] EWHC 2311	Shoes EP 0 858 270 EP 1 185 183	Floyd J	Yes as to 270 (as to declaration sought). No as to 183	Yes x 2	Yes, pending



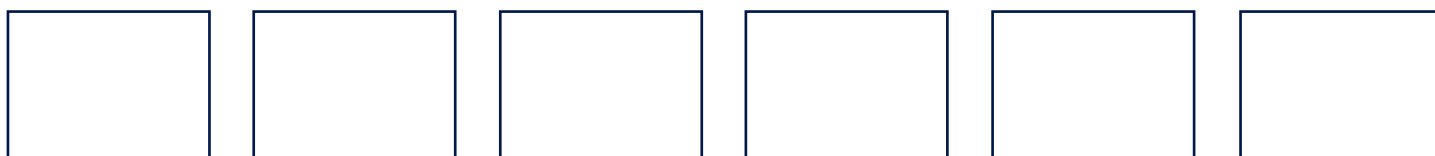
Patents Court and Patents County Court Judgments on Validity and Infringement for 2008

Date	Parties	Citation	Subject matter	Judge	Infringed	Valid?	Appealed?
13.10.2008	Dr Reddy's Laboratories (UK) Limited v Eli Lilly & Company	[2008] EWHC 2345 Pharmaceutical: Olanzapine	EP 0 454 436	Floyd J	N/A	Yes	Yes, pending 11/09
15.10.2008	Generics (UK) Ltd v Daiichi Pharmaceutical Company & anr	[2008] EWHC 2413	Pharmaceutical: Levofloxacin EP 0 206 283 & SPC (GB97/085)	Kitchin J	N/A	Yes	Yes, pending
21.10.2008	Ancon Limited v ACS Stainless Steel Fixings Limited	[2008] EWHC 2489	Steel channel assembly EP 0 882 164	Patten J	No	Yes	Yes, pending
14.11.2008	Armour Group plc v Leisuretech Electronics Pty Ltd	[2008] EWHC 2797	Distributed Audio System EP 1 004 221	Arnold J	Admitted	No - Obvious	[No]
16.12.2008	Ratiopharm GmbH v Napp Pharmaceutical Holdings Ltd Sandoz Ltd v Napp Pharmaceutical Holdings Ltd	[2008] EWHC 3070	Pharmaceutical: Oxycodone formulation EP 0 722 730 EP 1 258 246	Floyd J	No x 2	Yes x 2	Yes [2009] EWCA 252 Reversed: infringement Upheld: validity



Court of Appeal Judgments on Validity and Infringement in 2008

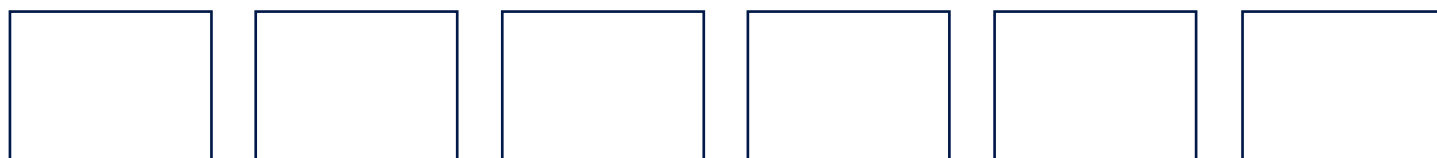
Date	Parties	Citation	Subject matter	Judge Upheld?	Infringed	Valid?	Appealed?
19.03.2008	European Central Bank v Document Security System	[2008] EWCA 192	Anti-copying device EP 0 455 750	Yes	N/A	No - Added matter	No
14.04.2008	Generics & Ors v H Lundbeck AS	[2008] EWCA 311	Pharmaceutical: Escitalopram EP 0 347 066	No	N/A	Yes	Yes. Upheld [2009] UKHL 12
21.05.2008	Actavis v Merck	[2008] EWCA 444	Pharmaceutical: Finasteride EP 0 724 444	No	N/A	Yes	Pending outcome of the EPO reference to EBA in KOS
09.05.2008	Servier v Apotex	[2008] EWCA 445	Pharmaceutical: Perindopril EP 1 296 947	Yes	N/A	No - Anticipated	No
30.07.2008	Handicraft Company & ors v B Free World Ltd & ors	[2008] EWCA 868	Baby bottles EP 0 845 971	Yes	N/A	No - Obvious	No
22.10.2008	Thorn Security v Siemens Schweiz	[2008] EWCA 1161	PCB Coating EP 0 577 094	No	No - reversing judgment	Yes - but not in issue on appeal	No
29.10.2008	Qual-Chem Ltd v Corus UK Ltd	[2008] EWCA 1177	Steel Making Process GB 2 363 635	Yes	Yes	Yes	No



Patents Court and Patents County Court Judgments on Validity and Infringement for 2009

Date	Parties	Citation	Subject matter	Judge	Infringed	Valid?	Appealed?
09.01.2009	Corevalve Inc v Edwards Lifesciences AG and anr	[2009] EWHC 0006	Medical Device: Artificial heart valve EP 0 592 410	Prescott QC	No	Yes	Yes, pending
16.01.2009	Actavis UK Ltd v Novartis AG	[2009] EWHC 0041	Pharmaceutical: fluvastatin formulation EP 0 948 320	Warren J	N/A	No - Obvious	Yes, pending
19.01.2009	Schlumberger Holdings Ltd v Electromagnetic Geoservices AS	[2009] EWHC 0058	Oil Exploration: method EP 1 256 019 EP 1 309 887 GB 2 399 640	Mann J	N/A	No x 3 - Obvious	Yes, pending
21.01.2009	Virgin Atlantic Airways Ltd v Premium Aircraft Interiors Group Ltd and anr	[2009] EWHC 0026	Aircraft Seats EP 1 495 908	Lewison J	No	Yes	Yes, pending 10/09
22.01.2009	Dyson Technology Ltd v Samsung Gwangju Electronics Co Ltd	[2009] EWHC 0055	Vacuum Cleaners GB 2 424 603 GB 2 424 606	Arnold J	N/A	No x 2 - All claims in 603 and 606 in issue obvious and claim 1 of 603 anticipated. Claim 1 of 603 as amended valid, and 2 new claims of 606 as amended permissible	?
23.01.2009	Laboratoires Almirall SA v Boehringer Ingelheim International GmbH	[2009] EWHC 0102	Pharmaceutical: Combination of aclidinium and B2 agonists EP 1 651 270 (Boehringer) GB 2 419 819 (Almirall)	HHJ Fysh	N/A	No x 2 - All claims obvious and claim 20 of 819 also invalid as method of medical treatment	?
12.02.2009	Ratiopharm (UK) Ltd v Alza Corp and anr; Alza Corp and anr v Sandoz Ltd	[2009] EWHC 0123	Pharmaceutical: Transdermal Patches for fentanyl EP 1 381 352	Kitchin J	Yes	No - Anticipated and obvious	?
26.02.2009	Belvac Production Machinery Inc v Carnaudmetalbox Engineering Ltd	[2009] EWHC 0292	Can Processing Machinery EP 0 767 713	Baldwin QC	No	No - Obvious	?
03.03.2009	Novartis AG v Dexcel-Pharma	[2009] EWHC 0336	Pharmaceutical: Cyclosporin Formulation GB 2 222 770 ¹	Arnold J	Yes	N/A	Yes, pending
11.03.2009	MMI Research Ltd v Cellxion Ltd & ors	[2009] EWHC 0418	Anti-GSM network security EP 1 051 053	Floyd J	Yes	Yes	?
27.03.2009	Scinopharm Taiwan Limited v. Eli Lilly & Company	[2009] EWHC 631	Pharmaceutical: Process for Making Gemcitabine EP 0 577 303	Kitchin J	N/A	Yes	?

¹ Previously in issue in Novartis AG v Ivax Pharmaceuticals UK Ltd [2006] EWHC 2506, [2007] EWCA Civ 971.



Europe: The current proposals for a European Patent Court

Introduction

The latest version of the Presidency's draft Agreement on the European and Community Patents Court was published on 23 March of this year. The Intellectual Property (Patents) Working Party met on 2 April to discuss this latest version of the draft Agreement.

Previous attempts to reach agreement on the judicial arrangements for a European and Community Patents Court have floundered for a variety of different reasons including but not limited to (1) concern over a non-sophisticated court making decisions with pan-European effect on the infringement and validity of patents covering highly technical subject matter; (2) the role of the ECJ in the court system and (3) the language in which the proceedings are conducted.

We consider below some of the key aspects of the latest version of the draft Agreement which have been designed to deal with these various concerns.

Jurisdiction

The draft Agreement establishes a European Patent Court which has exclusive jurisdiction to decide on the infringement and validity of European Patents as well as Community Patents (as and when they are granted). The Court would also have

exclusive jurisdiction over various ancillary matters such as Supplementary Protection Certificates and compulsory licences.

The Court itself would comprise Courts of First Instance with a central division as well as various local or regional divisions and a centrally based Court of Appeal.

There is a need for the ECJ to have a role in the functioning of the European Patents Court. This need arises because as with national patent litigation at present, questions of interpretation of the Treaty (e.g., Articles 28 and 30) or the validity or interpretation of Community law which impacts on the enforcement of patents (e.g., the Biotechnology Directive, the Enforcement Directive and the SPC Regulation) must be referred to the ECJ for an opinion.

Previous versions of the draft Agreement had provided that the ECJ should have an appellate jurisdiction in respect of actions brought before the European Patents Court. The concern here was that this would be counter-productive because (as seen in the trade mark field) the ECJ tends to be slow to render opinions and the opinions which it does render are often difficult to interpret in practice.

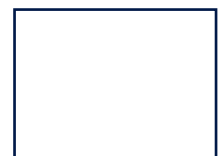
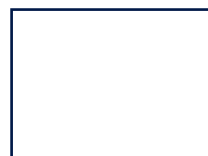
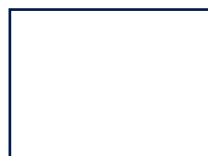
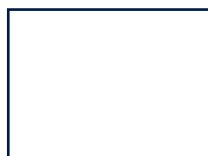
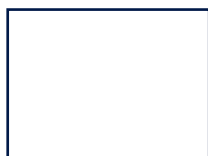
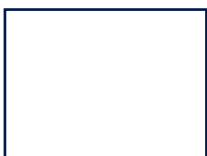
This concern appears to have been met in the latest version of the draft Agreement by limiting the ECJ's jurisdiction to questions of interpretation of the EU Treaty or the validity or interpretation of acts of EU institutions.

Judges

The Courts of First Instance comprise both a central division and various local or regional divisions. The concern about an unsophisticated court making decisions with pan-European effect on the infringement and validity of patents has been addressed in numerous ways.

First, the tripartite panel of Judges hearing the action whether in the central or a local or regional division is to be multinational. Second, the Judges from the Pool of Judges who are used to staff the central division and also supply the multinational element to the local and regional divisions are to include technically as well as legally qualified Judges. Third, the panels for the central division will always comprise two legally qualified Judges and one technically qualified Judge. Fourth, the local and regional divisions are given the power to request that a technically qualified Judge is appointed as the multinational Judge element from the Pool of Judges. Fifth, the local or regional divisions are given the power to transfer an action in which there is a revocation counterclaim to the central division (instead of requesting the appointment of a technical Judge from the Pool of Judges). Sixth, all revocation only actions will be heard by the central division. Seventh, there is provision for the setting up of a training programme for Judges so as to improve the patent litigation expertise of the existing as well as the future Judges.

Whilst many of these proposals have been well received, one which is causing some



disquiet is the jurisdiction given to the central division over revocation actions – forcing litigants to start revocation actions in the central division and giving local and regional divisions the power to transfer revocation counterclaims to the central division whilst the infringement action is stayed will in both cases have the potential to cause delay and thereby also increase costs.

Language

The provisions regarding language are intended to enable the Contracting States or failing that the court or failing that the parties to opt for the language of the proceedings to be that in which the patent was granted or failing that one of the three official languages of the EPO i.e., in both cases English, French or German.

Thus, (1) the language of the proceedings at the central division shall be the language in which the patent was granted, or (2) the parties can agree to the language of the proceedings being that in which the patent was granted and if the local or regional division does not agree with that decision, the case can be transferred to the central division, or (3) the local or regional division can themselves decide on the language of the proceedings being that in which the patent was granted on grounds of fairness and convenience, or (4) the Contracting States may designate one or more of the official languages of the EPO as the language of proceedings of their local or regional division. Failing that, the language of the proceedings before a local or regional division is the official language

of the Contracting State or States hosting the local or regional division or the official language designated by the Contracting States sharing a regional division.

In practice, the language of most proceedings is likely to be English, French or German. There is however the possibility that it will be another less widely spoken official language of a Contracting State in which translations and interpretation would be required throughout for at least one of the parties to the proceedings.

Fees/costs

The draft Agreement specifies that the Court fees shall be fixed at such a level to ensure the right balance between the principle of fair access to justice and an adequate contribution of the parties for the costs incurred by the Court. It remains to be seen how much users will be charged for using the new European Patents Court.

The economic rationale for establishing the European Patents Court would appear to be based on the assumption that it would be able to deliver litigation for roughly the same cost as the three largest low-cost European national systems namely Germany, France and The Netherlands.

If that assumption is correct (which obviously would remain to be seen in practice) and also assuming that litigation of European Patents before the European Patents Court becomes compulsory (which as explained below is what is envisaged in the draft Agreement), then for those

companies that can afford to litigate in only one of those low cost national systems, litigation would no longer be an option because they could not afford it and for those companies that can bear the cost of litigating in many jurisdictions, they would lose the tactical advantage of so doing. For those companies that can afford to litigate in a few jurisdictions but do not wish to obtain any tactical advantage from litigating in many jurisdictions, litigation before the European Patents Court would have the potential to offer a costs advantage.

Whether in practice however litigation before the European Patents Court would offer users an advantage over the current national litigation systems would seem to depend upon the circumstances of the parties to the action being litigated and the nature of that action.

Transitional provisions

Although the transitional provisions come at the end of the draft Agreement, in many respects, they represent the starting point of a consideration by user as to whether the new European Patents Court will be a good thing.

There are two aspects to the transitional provisions. The first is that for a period of seven years after the Agreement comes into force, infringement and revocation actions can be initiated as now before the national courts of the Contracting States. The second is that, provided that they notify the Court's Registry more than one month before the expiry of the seven year



transitional period, patentees have the right to opt out of the Agreement in relation to those patents and patent applications which were granted or pending as at the end of the seven year transitional period.

After the end of the seven year transitional period therefore (subject to the right to opt out in relation to their then granted patents or pending patent applications) patentees will be obliged to litigate their European Patents before the new European Patents Court. Although as explained above, it is envisaged that there will be several if not many first instance courts or divisions, the rules under which they will be operating will essentially be the same.

For the reasons explained above, there are likely to be a significant number of patentees who, given the choice, might not necessarily choose to litigate their European Patents before the new European Patents Court but would prefer the flexibility offered by the current national litigation systems. The problem from the point of view of the Commission (and indeed the Contracting States) however is one of cost. To help the Court pay its way, the Commission is intent on obliging users to litigate their European Patents before the new European Patents Court and by so doing, ensure that they contribute towards the costs of establishing and running it.

Future progress

On 20 March 2009, the Commission issued a recommendation that the Council authorise the Commission to open negotiations for the adoption of an Agreement creating a Unified Patent Litigation System. If the recommendation is accepted then discussions concerning the Community Patent and European/Community Patents Court will commence in earnest again.

It obviously remains to be seen whether the Commission can persuade the users that the latest set of proposals will deal with their historical concerns and provide a litigation regime which is as, if not more, fair, efficient and cost effective than the existing national litigation system.

Neil Jenkins, London

France: Implementation of the Enforcement Directive

The implementation in France of Directive 2004/48/EC on the Enforcement of Intellectual Property Rights has introduced various new provisions into the French patent law.

As will be seen below, the French courts are still coming to grips with the practical effect of these changes to the law.

Evidence gathering: "Saisie-contrefaçon"

There are some key changes relating to the "saisie-contrefaçon", which is the most powerful way to gather evidence of infringement in France.

Firstly, whereas the former law only provided for the description or the seizure of samples of products allegedly in infringement of a patent, the new law provides for the seizure of all products or processes allegedly in infringement.

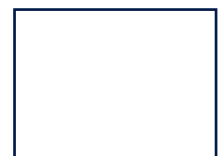
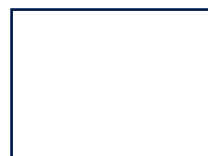
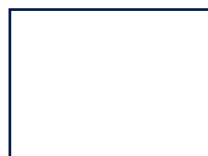
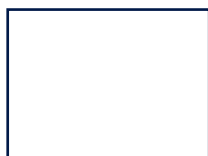
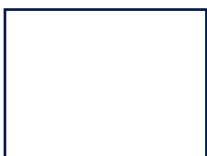
It is anticipated that despite the change in the law, it will still be applied restrictively.

Secondly, the new law has now provided for the seizure of materials and equipment used in the production and/or distribution of the alleged infringing products as well as documents relating to such materials and equipment.

Finally, a Decree dated 27 June 2008 provides that following a saisie-contrefaçon, an action on the merits must be started within a period not exceeding 20 working days or 31 calendar days, whichever is the longer as from the date of the "saisie". Under the former law, the specified period of time was 15 days.

Provisional and precautionary measures

There are six major changes relating to orders for provisional and precautionary measures.



First, preliminary injunctions can be granted on the basis of an ex-parte application and not only an inter-partes application as was case under the old law.

Secondly, urgency is no longer a pre-requisite to the grant of a preliminary injunction.

Thirdly, as with application for a saisie-contrefaçon, an action on the merits must now be started within a period not exceeding 20 working days or 31 calendar days from the date of the order granting the preliminary injunction. Under the old law, preliminary injunctions could only be requested after the start of the action on the merits.

Fourthly, preliminary injunctions can now be granted to prevent an "imminent infringement", not merely to prevent an actual infringement.

Fifthly, the action on the merits no longer needs to "appear serious" – previously this was the standard which had to be met by an applicant. Under the new law however the applicant has to provide "reasonably available proof that make likely the actual infringement of the applicant's right, or that such infringement is imminent".

Finally, preliminary injunctions can now be made not merely against the infringer of an IP right but also against any intermediary whose services are being used to facilitate the infringement of that IP right.

The new law in practice

On 21 July 2008, before the First Instance Court of Lyon, Bird & Bird Paris obtained for the first time in France a preliminary injunction preventing an imminent act of infringement that it was alleged was likely to be committed by a generic pharmaceutical company. The imminent act of infringement consisted of the upcoming launch of a generic version of a drug onto the French market which it was alleged infringed a patent still in force. In its decision, the First Instance Court of Lyon pointed out the defendant's arguments relating to the invalidity of the patent in suit were not to be considered as part of the court's assessment of the "likely of infringement".

On 20 January 2009 before the First Instance Court of Paris, in a similar case, but involving different parties, the preliminary injunction was refused. In that case, the First Instance Court considered that the fact that the generic pharmaceutical company has raised serious arguments regarding the validity of the patent required an examination of the merits.

Appeals have been lodged against both decisions and are still pending.

Right of information

The French Code of Civil Procedure already provided a "right of information". However, the new law that literally implements the relevant provision of the Enforcement Directive into the Intellectual Property Code introduced a change that

has caused an increase in the number of such claims being made to the Courts.

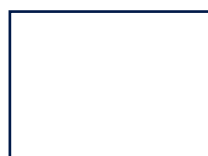
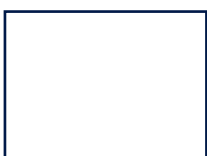
French case law on when such relief can be granted is confused as a result of contrasting decisions from the first and the second section of the third chamber of the First Instance Court of Paris, both of which have jurisdiction on patent matters.

The second section considers that a Right of Information order can be granted even before a decision on the merits acknowledging infringement (see Order of the President of the First Instance Court of Paris 21 March 2008 rendered in a trade mark matter but also applicable in patent matters), whereas the first section considers that a Right of Information order can only be granted after a decision on the merits acknowledging infringement (see Order of the President of the First Instance Court of Paris 19 November 2008).

Damages

In relation to the assessment of the damages, the main change is that the new law provides that profits accrued by the infringer shall be taken into consideration when deciding how much to award to the patent holder. Under the old law, the patent holder could only expect to receive compensation for the prejudice that he actually suffered, that is to say, lost profits or a reasonable royalty.

There is as yet no case law applying this new provision as it is only available for infringing acts happening after the entry into force of the new law.



Until now, the licensee of a patent could not obtain compensation for the prejudice which it had suffered, unless the licence agreement had been recorded in the national patent register. Under the new law, the recording of a licence agreement is no longer a condition for a licensee joining an infringement action initiated by the patentee. Accordingly, a licensee, whose licence agreement has not been registered, can nevertheless voluntarily intervene in an action and if the action is successful, he can then seek compensation from the alleged infringer for the damages suffered by him.

New opportunities for claim limitation

Under the old law, apart from one very uncommon exception, it was not possible to amend the claims of a granted patent. Obviously, under the EPC, amendments to a European patent could be made during the course of opposition proceedings and also since the adoption of EPC 2000, amendments could be requested to be made at any time.

Under the new law, however, a patentee can now file a request for the amendment of the claims of a French national or European patent either on its own or in the course of nullity proceedings. If granted, the amendment takes effect retrospectively.

The intention of the French legislators was to provide patent holders with the opportunity to amend claims and thereby allow them to clarify the scope of protection of patents and as a result,

increase the efficiency of the patent system in France.

Yves Bizollon, Lyon and
Florent Giulbot, Paris

Germany: Patent infringing offer without delivery capacity and literal patent infringement – Higher Regional Court of Düsseldorf decision in “occlusion means”

The Higher Regional Court of Düsseldorf recently confirmed German case law according to which an offer of a patent infringing product constitutes patent infringement, regardless of the infringer's intention or capacity to actually deliver the product (“Occlusion Means” decision of 22 December 2008, file no. I-2 U 65/07).

The subject of the proceedings were certain medical devices, i.e. intravascular occlusion means used for blocking a patient's vessel such as to prevent blood flow through an artery to a tumour or other lesion. The defendants had *inter alia* advertised such occlusion means on the internet.

The characterising portion of one of the patent claims at issue was directed to “clamps adapted to clamp the strands of the opposed ends of the device”.

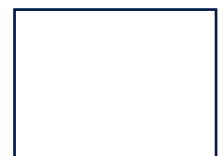
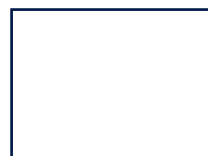
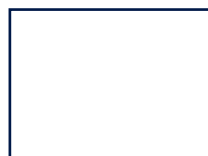
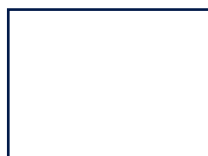
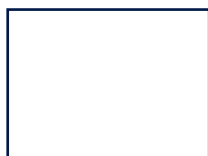
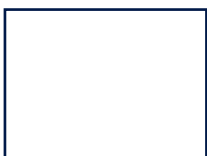
The defendants had argued that the products had not yet been marketed at the time of the internet advertisement due to a lack of capacity to deliver the product and therefore that no actual offer had been made at all.

The court rejected the defendants' argument stating that the mere act of offering the product as such is one which shall be reserved to the patentee. This is in line with the Federal Supreme Court decision “Simvastatin” of 5 December 2006 (GRUR 2008, 221), in which an advertisement for a product during the lifetime of a patent, but expressly intended for sale after expiration of a patent, was also held to be an infringing offer in terms of patent law.

The defendants furthermore argued that the above mentioned claim was directed to a device having more than one clamp since it claimed “clamps” (plural). Their embodiment, however, would merely make use of one single clamp.

The court decided that this did not mean that the defendant's device was not within the protective scope of the patent claim in terms of literal infringement. The claim needed to be interpreted in a technical, not merely philological sense, applying the common understanding of a person skilled in the art.

The word “clamps” used in plural would just be an indication of a certain category of means. The skilled person would interpret the claim at issue in such manner that clamps should be used where free



ends of wire strands were present in order to prevent them from fraying. Therefore he would understand the claim also to encompass a device only showing one end of such wire strand because both ends of the strands had been bundled together requiring only one clamp to be used as protection against undesirable fraying.

The Higher Regional Court of Düsseldorf thus confirmed the interpretation of the Regional Court holding that the claim was literally infringed. The Higher Regional Court did not feel any need to apply the doctrine of equivalents to find infringement.

The defendants additionally argued that the patentee had waived its right to patent protection for such embodiments as a result of what had been said in the course of the patent prosecution proceedings.

The Higher Regional Court also rejected this objection. Statements made in documents from the prosecution should not be used to interpret the meaning or scope of claims under Article 69 of the EPC or the corresponding German provision. The person skilled in the art could only rely on the technical teaching as documented in the published patent specification.

The defendants also submitted in evidence the existence of a further patent which they alleged would cover their embodiment. The court did not review this any further. Consistent with previous German case law, the court held that for the purpose of determining the question of literal infringement, it was no relevance

that a (further) patent had been granted for the infringing embodiment.

In summary, this decision of the Higher Regional Court of Düsseldorf deals with several important aspects of German patent law and as a result is likely to be relied upon by litigants in patent actions in the future.

Anna Wolters, Düsseldorf

Italy: Preliminary Injunctions in pharmaceutical patent actions

By a decision of 15 April 2009 issued in a preliminary injunction proceeding, the Court of Milan held that the mere grant of a Marketing Authorisation (MA) for a generic pharmaceutical product does not constitute an imminent threat of patent infringement.

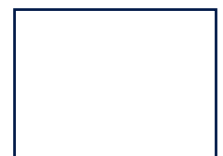
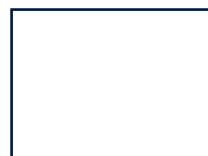
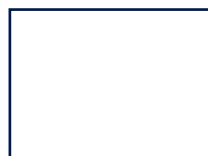
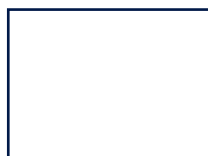
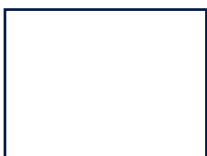
According to the Italian Intellectual Property Code *"whatever the subject matter of the invention, the exclusive right granted by the patent right shall not extend: a) to acts performed in private and for non commercial purposes, or for experimental uses even though aimed at obtaining, even in foreign countries, the authorisation for the commercialisation of a medical product and for the subsequent practical fulfilment, including therein the preparation and the use of the pharmacologically active raw materials strictly necessary for that purpose (...)"*.

It has been a matter of debate whether the grant of an MA alone constituted an act of patent infringement.

The only recent decision on the issue, also issued in the course of a preliminary injunction proceeding, was rendered by the Court of Rome. In that case, the Court of Rome held that the application for the MA had to be considered as an act of patent infringement. This decision has been highly criticised, among other reasons, because it relied on case law rendered before the change made to the Intellectual Property Code as set out above.

The decision of the Court of Milan, which is still subject to an appeal, was rendered in an application for a preliminary injunction made by Novartis AG against Mylan s.p.a. and Generics UK Ltd. Novartis alleged that the filing of an application for, and then the subsequent grant of the MA for a generic version of fluvastatin, interfered with the scope of protection of its fluvastatin formulation patent and implied an imminent threat of damage such as to justify the court granting a preliminary injunction against the two generic companies.

In rejecting the application for the preliminary injunction, the Court of Milan affirmed that *"the mere acquisition of the regulatory title required for the commercialisation of the generic drug is not enough, given that it does not per se imply an effective and concrete start of the marketing activity"*.



The Judge stated that a threat of imminent infringement could, for example, consist of the warehousing of the product or of the beginning of a marketing campaign at medical institutions. However, he pointed out that no such activity was even mentioned by the patent owner in this case.

Moreover, the Judge stated that the preliminary relief being requested would mean in effect the non-application of the regulatory measures under which the MA was granted. He said that this outcome would be highly questionable both with regard to the jurisdiction of a Civil Court and also with regard to the fact that the law provides an exception to infringement namely activities connected to the practical requirements aimed at obtaining an MA.

Licia Garotti, Milan

The Netherlands: EP 2000 improves patentee position

The Netherlands is generally seen as an attractive jurisdiction for litigating patent disputes, particularly because of its specialised patent courts and the procedural system, which can provide for a rather quick and substantial assessment of infringement and validity disputes.

A defendant can, inter alia, defend its position vis-à-vis the patentee by arguing invalidity of the patent. For this purpose, he will generally have to institute a

revocation action against the patent in The Netherlands. Such a revocation action can be instituted by writ of summons in a new action, or as a counterclaim in pending infringement proceedings on the merits.

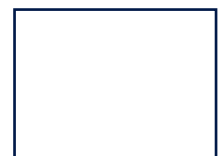
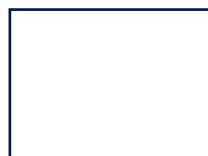
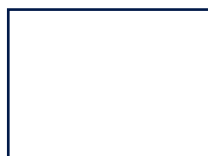
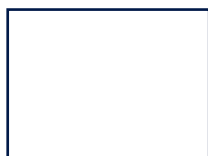
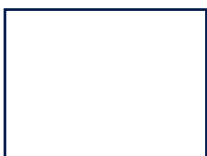
For the patentee, it is obviously important to remain flexible during the revocation action. New prior art may pop up, i.e. prior art that has not previously been seen during prosecution, and Dutch court may also have a different opinion to the EPO's as to the assessment of known prior art. The patent may come under serious threat, and in such event the patentee should have as a fall back position that if there would be reason to revoke, it should not be of the patent in its entirety, but only partially, ensuring a maintenance of the patent to the extent considered valid.

The Dutch Patent Act does provide a basis for a partial revocation. However, contrary to the position in many other contracting States to the European Patent Convention (EPC), in 1996 The Netherlands formulated additional criteria for the maintenance of patents in a modified form revocation proceedings: criteria that are not part of the traditional criteria for validity as set out in Article 138 EPC (novelty, inventive step, etcetera). A failure to meet these additional criteria would lead to revocation of the patent in its entirety.

These additional criteria were introduced by the Dutch Supreme Court in its decision of 9 February 1996 in the case *Spiro v Flamco*, and maintained by the same court in a subsequent decision of 16 February

2001 in the case *Wiva v Van Egmond*. Partial nullification and a modified maintenance of a patent was "only permitted if it is sufficiently clear to the average person skilled in the art who takes note of both the patent specification and the state of the art on the priority date where the boundaries of the protection are that are provided by the patent, if valid. For this, it is not only required that afterwards an amendment of the patent can be formulated, which draws these boundaries with sufficient clarity, but also that it is an amendment that was already sufficiently obvious to the average person skilled in the art beforehand to independently come to the conclusion, on the basis of the contents of the patent in conjunction with the state of the art on the priority date, that the patent should only have been granted with the restriction in that amendment and that it was therefore valid within the narrower boundaries to be derived from this". The criteria have been derived on the one hand from the statutory requirements (Article 75(1)(a-d) Dutch Patent Act) and on the other hand from the justified interests of third parties, also in connection with the retroactive effect of the revocation. The *Spiro/Flamco* doctrine has been applied since 1996 in a variety of cases, and has been the subject of criticism ever since.

With the entry into effect of EPC 2000 on 13 December 2007, this has however changed, at least as far as it concerns European patents. In any case for such patents, the so-called *Spiro/Flamco* doctrine no longer applies.



The first court to decide so was the Hague first instance patent court in its decision of 8 October 2008 in the case *Boston Scientific v EGP*. The court concluded that the Spiro/Flamco doctrine can no longer be maintained in the light of the changes to Article 138 under EPC 2000. This provision, which sets out under which limitative grounds European patents may be revoked, has direct effect in the contracting states of the EPC.

First of all, the court considered that new subsection 3 of Article 138 EPC determines that in case of a validity attack, the patentee has the **right** to limit the patent by amending the claim.

Furthermore, whilst subsection 1 of the old Article 138 EPC determined that "*Subject to the provisions of Article 139, a European patent may only be revoked under the law of a Contracting State, with effect for its territory, on the following grounds [...]*", new subsection 1 no longer comprises this reference to national law: "*Subject to Article 139 a European patent may be revoked with effect for a Contracting State only on the grounds that [...]*"

With reference to the *travaux préparatoires* of EPC 2000, the Hague patent court held this amendment to be of material importance, providing a more drastic harmonisation of (national) revocation actions than under the old EPC. The court concluded that this harmonisation not only served to make partial revocation possible in each and every contracting state, but also to exclude that contracting states will formulate

additional criteria to those already comprised in article 138 EPC. An extra pointer for this conclusion was found in the amendments of subsection 2 of Article 138 EPC. Whilst under the old EPC, subsection 2 of Article 138 provided "*If the national law so allows, the limitation may be effected in the form of an amendment to the claims [...]*", subsection 2 of Article 138 under EPC 2000 now provides that "*the patent shall be limited by a correspondent amendment to the claims and revoked in part*".

Since its decision of 8 October 2008, the Hague first instance patent court has in at least 3 subsequent decisions followed the same reasoning.

Recently, it was up to the Dutch Supreme Court to decide upon the fate of the Spiro/Flamco doctrine after the entry into force of EPC 2000. Although the case had to be assessed under the old EPC, the Dutch Supreme Court did add to its considerations, on basis of the reasons set out above, that with the entry into force of EPC 2000 the additional Dutch criteria for partial revocation and modified maintenance of European patents no longer apply. With that, in any case as far as it concerns European patents, the heavily criticised Spiro/Flamco doctrine is finally laid to rest.

Marc van Wijngaarden, The Hague

Spain: Preliminary injunctions in patent actions - recent judicial decisions

1. Background to preliminary injunction applications in Spain.

a. Applicable law

The procedure for obtaining a preliminary injunction in a patent action in Spain is governed by Articles 133 to 139 of the Spanish Patents Act 11/1986 (PA) and Articles 721 et seq of the Spanish Civil Procedure Act 1/2000 (CPA).

The specific injunctions to be requested by a patent holder against a third party are foreseen in Article 134 PA, whilst the procedural stages and general requirements of a preliminary injunction as such are regulated by the CPA.

b. "Periculum in mora" and "Fumus boni iuris"

There are two prerequisites to any claim for a preliminary injunction (i) the existence of a danger in delay ("*periculum in mora*") and (ii) a prima facie case that the patent is valid and infringed ("*fumus boni iuris*").

The "*periculum in mora*" requirement means that the claimant has to prove that the activity of the alleged infringer has caused the claimant damage, and that delay may cause the final judgment to lack any effectiveness.

The "*fumus boni iuris*" requirement means that the claimant has to prove that he is



entitled to enforce his alleged rights and there are good reasons to believe that these rights are being infringed by the defendant. When assessing this second requirement, the Court does not analyse the issue of infringement in detail but merely considers whether, in light of the evidence, it appears that his rights are being infringed. Accordingly, the decision issued by the Court in this regard does not prejudge the issue in the main action.

c. "Use of the patent"

The PA establishes a third requirement specific to claims for a preliminary injunction in a patent action. Article 133 PA states that a preliminary injunction claim based on an infringement of a patent can only be made when the patent is used by its holder, or at least, when serious and real preparations have been made by the holder to do so.

d. Bond and counter-bond

Pursuant to Article 728.3 CPA, the claimant is obliged to offer a bond to cover any damages caused to the defendant by the granting of the injunction should the defendant win the main action. The amount of this bond is hard to assess since it depends on a number of factors such as the nature of the injunction being claimed and the extent of the infringement taking place.

The bond is filed with the claim for a preliminary injunction specifying both the nature and the amount of the bond.

Where the court decides not to grant the injunction, it specifies the amount of the counter-bond to be provided by the

defendant at the time of hearing the preliminary injunction claim.

2. Recent judicial decisions issued by the Spanish Commercial Courts

Several decisions have been issued recently regarding preliminary injunction applications filed by patent holders in actions concerning pharmaceutical patents.

The 28th Section of the Appeal Court of Madrid, the specialist chamber which hears appeals in patent actions, heard an appeal on 16 April 2008 regarding the medicinal product venlafaxine. The claimant was the patent holder of a product patent for a sustained release form of venlafaxine and alleged the patent was infringed by a generic sustained release capsule containing the same active ingredient.

At first instance the Court considered that the preliminary injunction claim complied with the requirements of "*periculum in mora*", "*fumus boni iuris*" and "use of the patent" by the holder. The Court based its decision on the fact that the function of the excipients in the generic product were intended to permit the same effect as the product the subject of the claim i.e. the sustained release of the active ingredient.

On appeal, the first instance judgment was revoked on the following grounds:

- The fact that the generic products contained venlafaxine was irrelevant since the patent on that active ingredient had already expired.
- The excipients and their function in the composition of the generic product were not the same as those in the claim.

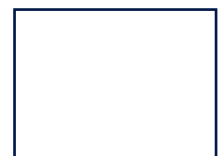
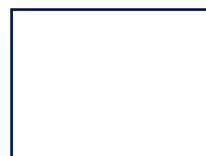
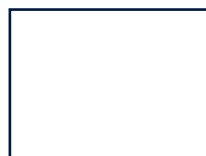
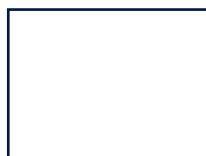
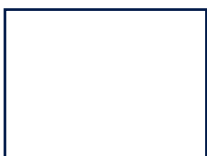
- Sustained released compositions were well known and the claim did not cover a sustained release form of venlafaxine *per se*.

The Appeal Court judgment also analysed all of the arguments raised by the parties on the issue of infringement by equivalents.

The Court established that the infringement cannot be based on an interpretation of the claims where the elements that are not included in the claims seem to be more relevant than the technical features that are included. It was held that the claimant had disregarded the content of the claims, using it as a mere starting point, and had included within their scope any product reproducing the same basic ideas and obtaining the same basic result. The Appeal Court asserted that the doctrine of equivalents cannot be applied in a wide manner and that the comparison between the alleged infringing product and the patent shall be made "element by element". It was established that the patent's scope is not the result obtained, but the way it is obtained.

When assessing the actual alleged infringement by equivalents in this case, the Court addressed two specific issues:

- one of the arguments raised by the claimant's expert was that the modifications introduced into the infringing products (as compared to the features of the claim) did not provide any additional development other than the state of the art. The Court considered that this was not relevant to the assessment of the alleged infringement. They held that the product in issue



needed to reproduce, literally or by equivalents, all the features of the patented invention and that, it was irrelevant whether or not any difference between alleged infringement and claim was inventive or not.

- as regards the scope of protection of the claims, the Court reviewed carefully the description of the patent to find out (i) the technical problem the invention was intended to solve and (ii) the role played by the excipients and the active ingredient in the alleged infringing product.

The Appeal Court held that the generic product did not infringe the patent because their composition and the function of their excipients differed from those claimed in the patent.

Another judgment by the **28th Section of the Appeal Court of Madrid on 18 October 2007** concerned a procedure initiated by a pharmaceutical company in respect of the launch of a generic product containing ebastine.

Although the patent covering ebastine had expired in March 2005, the patentee argued that the alleged infringing acts had begun in December 2002. On that basis, the patentee wanted the Court to examine whether their patent had been infringed while it was still in force. It was also argued that the failure by the defendant to file any samples of the product during the assessment of the Marketing Authorisation (MA) before the Spanish Medicines Agency, was an act of unfair competition since the defendant would have obtained an MA

without running the risk of being sued for patent infringement.

The preliminary injunction claim was rejected both by the Court of First Instance and by the 28th Section of the Appeal Court of Madrid.

With regard to the issue of patent infringement, the Appeal Court commented that the patentee's right to exclude third parties from infringing its rights was directly related to the existence of the patent. Moreover, it noted that Article 133 PA foresees the exploitation of the patent as one of the requirements to file a preliminary injunction claim. Therefore, it held that "*a preliminary injunction cannot be claimed against a third party outside the duration of the patent*".

With regard to the issue of unfair competition, the Appeal Court held that the acts performed before the Spanish Medicines Agency in order to obtain an MA for a generic product during the validity of a patent cannot be considered an infringing act even if product samples were filed with the MA application. Referring to the "Bolar" exemption, the Appeal Court held that "the preparation of samples, the performance of equivalence tests and the filing of MA applications before the expiry of a patent shall not be considered acts of infringement". Therefore, the defendant was not placed in a better position and did not obtain any competitive advantage by not filing the samples.

One of the most important aspects of patent litigation in Spain is that of the expert reports. Since the Spanish

Commercial Courts do not have Judges with a technical background, the reports filed by persons skilled in the art become the touchstone to decide whether the "*fumus boni iuris*" requirement is met in a patent preliminary injunction procedure. These reports must be filed at the very first stage of the proceedings, that is, together with the preliminary injunction claim.

It is sometimes difficult for the Judge to decide which report it is going to base its decision on, particularly when a court expert has not been designated. Should that be the case, the Court may take into account the expertise of and arguments raised by each of the experts. The outcome of the preliminary injunction claim will therefore often turn on the credibility of the expert reports filed by each side. This is why the **Commercial Court Number 1 of Madrid** rejected the preliminary injunction claim filed by the holder of a patent for "wheel socks" - devices designed to cover car wheels to perform a similar function to snow chains. Whilst the methods performed by the patentee's experts to measure the infringing products were based on subjective criteria, the tests performed by the infringer's expert were based on ascertained values and certified methods. The Court considered that the results shown in the defendant's report were more accurate than the ones reproduced in the patentee's report and decided to reject the claim. This decision was subsequently upheld by the 28th Section of the Appeal Court of Madrid.

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Beatriz Diaz de Escauriaza, Madrid



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