



The International Comparative Legal Guide to:

Patents 2016

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A practical cross-border insight into patents law

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1 Patent Enforcement

1.1 How and before what tribunals can a patent be enforced against an infringer?

There are three jurisdictions within the UK, namely England and Wales, Northern Ireland and Scotland. There are no specialist patents courts in Northern Ireland or Scotland although there are judges, advocates and lawyers with expertise in patents in these jurisdictions. The answers in this chapter address claims in England and Wales only. Patent infringement proceedings may be brought in the Patents Court (a division of the High Court) or the Intellectual Property Enterprise Court (IPEC) (formerly the Patents County Court), both of which are situated in London. The IPEC is intended primarily for smaller or simpler cases - its procedural rules are intended to make it a more accessible forum for small to medium size enterprises than the Patents Court. In the IPEC the total costs recoverable by a successful party are capped at £50,000 for the final determination of liability and at £25,000 for enquiries as to damages or accounts of profits, and there is a limit of £500,000 on the financial remedies available. Proceedings in both the Patents Court and IPEC are conducted before specialist patents judges. Infringement claims may alternatively be brought in the Intellectual Property Office (UK Patent Office) but only by agreement of the parties and injunctions are not available there, so the jurisdiction is little used. Proceedings are commenced: in the Patents Court by filing with the court a Claim Form with brief Particulars of the Claim; in the IPEC by filing with the court a Claim Form with Particulars of Claim setting out concisely all the facts and arguments relied upon; and in the Intellectual Property Office by filing a Patents Form 2 with a statement of grounds.

1.2 What are the pre-trial procedural stages and how long does it generally take for proceedings to reach trial from commencement?

The pre-trial procedural stages in the Patents Court consists of (i) service of the Claim Form on the defendant with Particulars of Claim and Particulars of Infringement showing which of the claims of the patent are alleged to be infringed with at least one example of each type of infringement alleged, (ii) service of a Defence (and Counterclaim with Grounds of Invalidity, if applicable), (iii) hearing of the Case Management Conference (CMC) before a judge, at which directions for the further conduct of the action are given, including deadlines for procedural steps and number of experts allowed, (iv) fixing of the trial date by the court listing

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office, (v) service of Notices to Admit and replies, to identify points that are not in dispute, (vi) exchange of lists of, and Disclosure of, documents relevant to the issues between the parties - a defendant may in lieu of giving Disclosure in relation to the alleged infringing product (or process) serve a Product (or Process) Description, (vii) carrying out of experiments permitted by the court to establish infringement (or invalidity), (viii) preparation and exchange of written factual and expert evidence, and (ix) provision to the court of skeleton arguments. In general, the trial will take place in 10 to 15 months from the commencement of proceedings. The pretrial procedure in the IPEC, in addition to the features identified in the answer to question 1.1, differs from that in the Patents Court in the following respects: (i) the defendant(s) is given more time (70 days instead of 42 days) to serve a Defence if the claimant has not sent a letter identifying his claim before commencing the action; (ii) all Statements of Case must set out concisely all the facts and arguments that are relied upon; (iii) save in exceptional circumstances (see the answer to question 1.5 below) the judge will not allow the parties to supplement their Statements of Case; (iv) there is no Disclosure of documents, unless ordered by the judge at the CMC; and (v) the extent (if any) that experiments, witness statements, experts' reports, cross-examination at trial and skeleton arguments are permitted is determined by the judge at the CMC.

1.3 Can a defence of patent invalidity be raised and if so how?

Yes. This can be raised as a defence and is normally also accompanied by a counterclaim for revocation, supported by Grounds of Invalidity, with copies of each document relied upon.

1.4 How is the case on each side set out pre-trial? Is any technical evidence produced and if so how?

The court is provided with (i) the Statements of Case (pleadings) including the Claim Form, Particulars of Claim, Particulars of Infringement, Defence (and Counterclaim if applicable, with Grounds of Invalidity), (ii) the patent(s), (iii) the prior art where invalidity is raised, (iv) Admissions, (v) Disclosure documents which the parties wish to rely upon and any Product (or Process) Description, (vi) factual witness statements, (vii) experts' reports, which may address any experiments that have been conducted, (viii) a technical primer, (ix) a guide for the judge's pre-trial reading with a time estimate for that reading, and (x) each party's skeleton argument. The parties are responsible for the preparation of bundles, including in the form of electronic or e-bundles, of these documents for the trial judge, which are generally provided about two weeks





before the trial. As indicated in the answer to question 1.2, (v) to (x) may not apply in a case in the IPEC.

1.5 How are arguments and evidence presented at the trial? Can a party change its pleaded arguments before and/or at trial?

Before the trial in the Patents Court, the judge will usually have read the documents indicated in the reading guide, namely the documents identified at (i), (ii) and (ix) in the answer to question 1.4, as well as the designated parts of (iii), (v), (vi) and (vii). The advocate for the claimant (usually a barrister, but sometimes a solicitor advocate) opens the trial with an address which follows and supplements the skeleton argument; at this stage and throughout the trial the judge will ask questions for clarification. The claimant's advocate then calls the claimant's experts and witnesses to briefly confirm their written evidence and then they are submitted to crossexamination by the defendant's advocate. Experts and witnesses may be cross-examined upon any document or issue in the case. At the conclusion of each cross-examination the claimant's advocate may put questions to the expert or witness by way of re-examination (without leading the expert or witness to the answer) of the oral evidence given in cross-examination. After closing of the claimant's evidence, the same process is followed for the defendant's evidence. The defendant's advocate then addresses the judge following and supplementing his skeleton argument as necessary in the light of the evidence given to the court. The claimant's advocate then closes the trial with an address which supplements his skeleton argument in the light of the evidence. In the IPEC, the court may determine the claim without a trial if all parties consent. If there is a trial, the Enterprise Judge will determine the amount of time allocated to each party (and for cross-examination of any of the witnesses and experts) and set the timetable so that the trial should not last more than two days.

An amendment of a party's case requires the consent of the adversary or, failing that, the permission of the court exercising its discretion to allow or disallow the amendment. Whichever route applies, an amendment is likely to be subject to conditions addressing matters such as (i) the costs of consequential amendments to the adversary's Statement of Case, (ii) the parties' costs of the case up until the time of the amendment, (iii) consequential directions for the conduct of the action including the timing of the trial, and (iv) the costs of adjourning any hearing or the trial. In general, in the Patents Court amendments will be allowed subject to a costs order which reflects the wasted effort caused by the late introduction of a new allegation or position. The position in the IPEC is slightly less permissive because: there is a costs cap in the IPEC, meaning the costs caused by the amendment will have greater significance than in the Patents Court; and similarly, the costs-benefit analysis of permitting amendments is more thorough. This means that litigants have to be more circumspect about being able to amend their case in the IPEC, meaning that formulating it correctly at the outset is important.

1.6 How long does the trial generally last and how long is it before a judgment is made available?

On average the trial will take three to five days, but the duration may be shorter in a very straightforward case or longer in a complex case where there is a need to hear evidence from several technical experts on each side. As indicated in the answer to question 1.5, in the IPEC there may be no trial at all (i.e. the case is decided upon the papers filed alone). A written judgment is generally handed down by the judge in four to eight weeks after the end of the trial.

1.7 Are there specialist judges or hearing officers and if so do they have a technical background?

Yes to both. In the Patents Court, 2 of the 10 designated judges have a science background and are normally allocated to cases with a higher technical difficulty rating. The appointment of a third technically experienced Patents judge has been recommended. The judge in the IPEC also has a technical background. There are also specialist patent judges in the Court of Appeal and in the Supreme Court.

1.8 What interest must a party have to bring (i) infringement (ii) revocation and (iii) declaratory proceedings?

- (i) The claimant must be the owner or co-owner of the patent or an exclusive licensee, and, if a co-owner or exclusive licensee, the other co-owner(s) or the owner must be joined to the proceedings.
- (ii) The claimant need not have any commercial or other interest.
- Declaratory proceedings fall into two categories: statutory (iii) proceedings (as set out in the Patents Act 1977); and proceedings under the court's inherent jurisdiction (whose scope is flexible). A person may seek a declaration that the performance of an act in relation to a product or process would not infringe a patent either on statutory grounds or under the discretion of the court: if the statutory grounds are used, the person must first provide the patent owner with full particulars of the act in question, seeking an acknowledgment that it would not infringe the patent; or if an acknowledgment is not provided, the person may bring proceedings for a declaration of non-infringement. A person may otherwise bring proceedings for such a declaration, in reliance upon the court's inherent discretion, if such a negative declaration (of non-infringement) is sufficiently well defined and would serve a useful purpose.

1.9 Can a party be compelled to provide disclosure of relevant documents or materials to its adversary and if so how?

Yes. Before the Jackson Reforms to civil procedure (as explained in the answer to question 8.2) each party was required to give 'standard disclosure' of documents in its control "relevant" to the issues in dispute. "Relevant" documents are those on which that party relies, those which adversely affect that party's case and those which either support or adversely affect the other party's case. Following the Jackson Reforms, such 'standard disclosure' is no longer the default position (although it remains an option). Parties must also consider whether alternatives to 'standard disclosure' may be more appropriate, including orders for disclosure only in relation to specific issues or an order dispensing entirely with disclosure. In patent proceedings 'standard disclosure' is usually ordered but modified so as to exclude the following classes of documents: (a) documents that relate to infringement where (in lieu) a product or process description is provided; (b) documents that relate to validity which came into existence more than two years before or after the earliest claimed priority date of the patent; or (c) documents that relate to commercial success. Disclosure is generally given by serving a list of all relevant documents on the adverse party (claiming legal privilege from production as necessary) and allowing inspection if required of the non-privileged documents (and copies upon request). Confidential documents which are not legally privileged must be listed and produced for inspection but may be protected by restrictions on disclosure and use by order of the court or agreement of the parties.

1.10 Can a party be liable for infringement as a secondary (as opposed to primary) infringer? Can a party infringe by supplying part of but not all of the infringing product or process?

Yes. A person infringes a patent where he supplies or offers to supply a person in the UK, other than a licensee, with any essential element of the claimed invention when he knows, or it would be obvious to a reasonable person in the circumstances, that this was suitable for putting, and intended to put, the claimed invention into effect in the UK. The supply of or offer to supply a "staple commercial product" is not an infringement unless it is made for the purposes of inducing infringement. Knowledge of the patent, actual or constructive, is not a pre-requisite for infringement (i.e. knowledge of the intended product or process is required rather than of the legal consequence) nor is knowledge of the intention of the ultimate user (it being sufficient that it would be obvious that some ultimate users would use the essential element so as to infringe).

It is also possible to join parties which have assisted in the infringement as joint tortfeasors by pleading procurement or common design.

1.11 Can a party be liable for infringement of a process patent by importing the product when the process is carried on outside the jurisdiction?

Yes. It is an infringement of a process claim to import any product obtained directly by means of the process claimed. The meaning of "obtained directly by means of the process" has been considered by the courts on a number of occasions and has been interpreted to mean: "the immediate product of the process", or, where the patented process is an intermediate stage in the manufacture of some ultimate product, that product, but only if the product of the intermediate process still retains its identity.

1.12 Does the scope of protection of a patent claim extend to non-literal equivalents?

Yes. Courts in the UK apply Article 69 and the Protocol on its Interpretation by giving patent claims a "purposive" interpretation, that is to say construing them in context, having regard to the inventor's purpose, through the eyes of the man skilled in the art using his common general knowledge. Given "purposive construction", overliteral interpretation of claims is avoided; and because of it there is no need for a "doctrine of equivalents" in the UK.

1.13 Other than lack of novelty and inventive step, what are the grounds for invalidity of a patent?

The principal grounds are (i) insufficiency (lack of enablement), (ii) lack of industrial applicability, (iii) extension of the subject matter in the specification during prosecution or opposition proceedings over and above the matter contained in the application as filed, (iv) extension of the scope of protection of the patent by a pre- or postgrant amendment to the claims that should not have been allowed, and (v) the patent was granted to someone not entitled to it.

1.14 Are infringement proceedings stayed pending resolution of validity in another court or the Patent Office?

The question of whether a stay of infringement proceedings (with or without a UK invalidity counterclaim) should be granted pending

resolution of validity of the patent in the European Patent Office (EPO) is a matter of discretion for the court to exercise addressing whether, on balance, a stay is in the interests of justice. (It should be noted that validity proceedings in the UK Intellectual Property Office are normally transferred to the court when an infringement action is commenced there, so there is no question of a stay then; and that validity of a corresponding patent in another country is generally considered to be irrelevant and so is not grounds for a stay in the UK.) The Court of Appeal has revised its guidance on when English patent proceedings should be stayed pending the outcome of opposition proceedings in the EPO: if there are no other factors, a stay of the national proceedings is now the default option. The onus is on the party resisting the grant of the stay to adduce evidence why it should not be granted. While the typically shorter length of time that it will take for the proceedings in the national court, as compared with the EPO to reach a conclusion remains an important factor affecting the discretion, this has to be considered in conjunction with the prejudice that any party will suffer from the delay, and what the national proceedings can achieve in terms of certainty. Two new factors are also taken into consideration: (i) the extent to which refusal of a stay will irrevocably deprive a party of any part of the benefit that the concurrent jurisdiction of the EPO and the national court is intended to confer (for example, if allowing the national court to proceed might allow the patentee to obtain monetary compensation that is not repayable if the patent is later revoked, this would be a factor in favour of the grant of a stay); and (ii) the fact that resolution of the national proceedings may promote settlement. The public interest in dispelling the uncertainty surrounding the validity of monopoly rights conferred by the grant of a patent remains a factor to be considered. In weighing the balance, the risk of wasted costs is material, but will normally be outweighed by commercial factors concerned with early resolution. Overall, the guidelines mean that the time delay inherent in EPO proceedings is to be given less weight than previously.

1.15 What other grounds of defence can be raised in addition to non-infringement or invalidity?

The right to continue to do something already done (or where effective and serious preparations to do such act were done) before the priority date of the patent can be raised as a defence. Such prior use must be in public, done in good faith, in the UK and personal as it does not extend to granting a licence to another person to do the act. The main other substantive defence is that the defendant has the benefit of, or is entitled to, a licence. This may be raised in various ways, depending on the factual and legal background. Statutory grounds for a licence may be available inter alia because (i) the patent owner has registered the availability of licences as of right, (ii) compulsory licences are available three years from grant of the patent where (a) broadly speaking, the invention or another invention "which makes a substantial contribution to the art" is not being commercially worked in the UK, or (b) the UK Intellectual Property Office has made a register entry against the patent that licences are available as of right as a result of a Competition Commission report to Parliament, and (iii) compulsory licences are available for service to the Crown: in each case subject to the payment of royalties (which are determined by the court in default of agreement by the parties, which in turn means that these provisions are hardly used). Contractual or quasi-contractual grounds for a licence may exist where the defendant and the patent owner are involved in some joint technology initiative or enterprise which explicitly or implicitly gives rise to entitlement to a licence, either on agreed terms or on terms to be agreed which are reasonable.

1.16 Are (i) preliminary and (ii) final injunctions available and if so on what basis in each case?

- (i) Preliminary (interim) injunctions are available and are granted if (a) there is a serious issue to be tried, that is to say there is an arguable case, (b) the "balance of convenience" favours an injunction or, all things considered, is even (this involves consideration of factors such as: the irreparability of the harm to the claimant and to the defendant respectively if an injunction were refused or granted; the adequacy of damages and ability to estimate damages payable to the claimant and defendant respectively if an injunction were refused or granted; and the proximity of the trial), and (c) the claimant gives a cross-undertaking to compensate the defendant in damages if the injunction is wrongly granted. In pharmaceutical cases where a defendant proposes to introduce a generic product, the claimant can normally show that there will be irreparable damage as a result of irreversible price erosion. In such cases interim injunctions are relatively common. However, if generic manufacturers lose the 'first mover' advantage as a result of an injunction wrongly granted, a liberal assessment of damages will be made under the cross-undertaking.
- Final injunctions are generally granted if the claimant (ii) is successful at trial unless this would be "grossly disproportionate". A stay of an injunction pending appeal, so as to permit the Court of Appeal to do justice whatever the outcome of the appeal, may be granted on the "balance of convenience principle"; and, if an injunction is granted or maintained pending appeal, the claimant may be required to give an undertaking to compensate the defendant if the injunction is lifted by the Court of Appeal. It is important to bear in mind that all injunctions are discretionary. Article 3(2) of the Enforcement Directive also requires the court to refuse to grant an injunction where it would be 'disproportionate' to grant one. Case law, however, confirms that in a patent case, where an injunction is the primary way of enforcing that right, the burden on a party seeking to show that the grant of an injunction would be disproportionate is a heavy one.

1.17 On what basis are damages or an account of profits estimated?

In the UK, the quantum of damages (or account of profits) payable by a losing defendant is always assessed after, and separately from, the trial on liability for patent infringement in a procedure called the inquiry as to damages. The claimant is given disclosure by the defendant at the start of this procedure to enable it to elect whether to pursue damages or an account of profits (a claimant cannot seek both). An account of profits is very rarely chosen in a patent action given the complexity of technical and commercial factors that contribute to a defendant's profits. Damages are estimated by the court at a hearing (effectively a trial) on the basis of the disclosure and expert evidence provided to it. The principles applied by the court, in simple terms, are (i) damages are only compensatory (not punitive), (ii) the burden of proof lies on the claimant but damages are to be assessed liberally, (iii) where the patent has been licensed, the damages are the lost royalty, (iv) it is irrelevant that the defendant could have competed lawfully, and (v) where the patent owner has exploited the patent by manufacture and sale he can claim (a) lost profits on sales by the defendant he would otherwise have made, (b) lost profits on his own sales to the extent that he was forced to reduce his own price, and (c) a reasonable royalty on sales by the defendant which he would not otherwise have made.

1.18 What other form of relief can be obtained for patent infringement?

The court may order (i) the delivery up or destruction of infringing goods, and/or (ii) appropriate measures for the dissemination and publication of the judgment, at the expense of the infringer (in compliance with the UK's obligations under Directive 2004/48/EC on Enforcement of IP Rights); an award of costs.

1.19 Are declarations available and if so can they address (i) non-infringement and/or (ii) claim coverage over a technical standard or hypothetical activity?

- (i) Yes, as indicated above (question 1.8).
- (ii) UK courts have a wide discretion to grant any form of declaratory relief (whether affirmative or negative) provided that the declaration sought is sufficiently well defined and that it would serve a useful purpose (in the sense that there must be a real commercial reason for the person seeking the declaration in order to have standing to do so). Thus, the Patents Court has been willing to grant negative declarations in favour of a mobile telephone handset manufacturer that certain telecommunications patents declared as "essential" to the implementation of certain ETSI standards are not in fact "essential" as purported by the patent owner. On the other hand, the court will be reluctant to entertain declaratory proceedings where there is no real prospect that the declaration sought will resolve a real (as opposed to hypothetical) commercial issue between the parties.

1.20 After what period is a claim for patent infringement time-barred?

The time period is six years from when the cause of action accrued. Where there is concealment of the infringement, the six-year limitation period does not start to run until the claimant discovers the concealment or could with reasonable diligence discover it.

1.21 Is there a right of appeal from a first instance judgment and if so is it a right to contest all aspects of the judgment?

A judgment may be appealed if the trial judge or the Court of Appeal (if the trial judge refuses permission to appeal) considers that the appeal has "a real prospect of success". The prospect of success must be realistic and credible. New evidence or material is not allowed on appeal unless it could not, with due diligence, have been found for use at the trial and even then it is only allowed when it is likely to have a material effect on the appeal. The Court of Appeal is always reluctant to interfere with findings of fact by the trial judge or with value judgments such as obviousness. This has the consequence that grounds of appeal should, wherever possible, identify errors of law or application of the law.

1.22 What are the typical costs of proceedings to first instance judgment on (i) infringement and (ii) validity; how much of such costs are recoverable from the losing party?

In the UK, infringement and validity are dealt with together, at the same trial. The typical cost of an action involving both infringement and validity is in the region of £350,000 to £650,000 depending on such matters as the number of patents/claims in dispute, the number and nature of the invalidity attacks, whether more than one expert is

required to give evidence at the trial. In more complicated actions involving extensive disclosure of documents or experiments then the cost will be higher and in some cases substantially higher. The judges are increasingly proactive in the exercise of their case management powers to reduce costs - see especially the comments on the procedures in the IPEC in the answer to question 1.1. In the Patents Court, following the introduction of wide-ranging procedural reforms a tear or so ago, parties must now prepare and exchange costs budgets (except where the value of the claim is certified to be £10 million or more). Costs budgets are designed to give the parties and the court visibility of the likely costs to be incurred by both sides and the opportunity for the court to manage them to ensure proportionality. Although the general rule is that costs follow the event and therefore that the overall winner can expect to be awarded their costs of the action, the Patent Court adopts an issue-based approach which means that in practice a discount will be made for the costs of those issues on which the winner lost. A party in whose favour a costs order is made would normally expect to recover approximately 65-75% of their actual legal costs the subject of that order. Where costs budgets have been employed the winning party is likely to recover 80-90% of those costs.

1.23 For countries within the European Union: What steps are being taken in your country towards ratification, implementation and participation in the Unitary Patent Regulation (EU Regulation No. 1257/2012) and the Agreement on a Unified Patent Court? For countries outside of the European Union: Are there any mutual recognition of judgments arrangements relating to patents, whether formal or informal, that apply in your country?

In the UK the legislative vehicle for introducing the UPC is the Intellectual Property Act 2014 which inserts a provision into the Patents Act 1977 permitting the Secretary of State to issue an order giving effect in the United Kingdom to the UPC Agreement.

The UK Government is committed to holding an in-out referendum on EU membership by 2017 but the IPO has expressly said that this will not delay preparations for the UPC. The UPC Preparatory Committee had previously stated that "UPC will not be operational until the end of 2015 at the earliest", but it is likely that operations will not now begin until 2016. In the meantime the UK is participating in the Preparatory Committee, for which it leads on IT matters, and in the EPO's Select Committee on the Unitary Patent.

2 Patent Amendment

2.1 Can a patent be amended *ex parte* after grant and if so how?

Yes, by applying for an amendment to the UK Intellectual Property (Patent) Office. The application is advertised by the UKIPO on its website and in its journal and third parties may oppose the amendment (so *ex parte* examination of the application is not in fact assured). Central amendment of the UK designation of a European patent in accordance with the European Patent Convention (EPC) is also possible via proceedings at the European Patent Office (EPO).

2.2 Can a patent be amended in *inter partes* revocation proceedings?

Yes. Amendment is at the discretion of the court and the validity of the patent as proposed to be amended will be addressed by the court before allowing it. If the patent owner fails to seek amendment before the patent is revoked at first instance he will generally be refused permission to amend on appeal, as this is regarded as an impermissible attempt to re-litigate issues that should have been addressed at first instance.

2.3 Are there any constraints upon the amendments that may be made?

The constraints are the same as those that apply under the European Patent Convention, namely that an amendment will not be allowed if it would extend (i) the subject matter over and above the disclosure contained in the application for the patent, or (ii) the extent of protection; or if it would not cure the ground of invalidity (if the amendment is made to cure potential invalidity). The amended claim must also be supported by the specification in the same way as during prosecution.

3 Licensing

3.1 Are there any laws which limit the terms upon which parties may agree a patent licence?

Yes, competition law (EU and UK) prohibits terms in a licence which are restrictive of competition in the relevant market, in the sense that the terms go beyond what the monopoly conferred by the patent accords to the owner or exclusive licensee. Thus terms such as price fixing, limitations on output, allocation of customers and restrictions upon the use of the licensee's own technology are potential violations of competition law. The penalties include unenforceability of the offending terms and/or fines.

3.2 Can a patent be the subject of a compulsory licence and if so how are the terms settled and how common is this type of licence?

Yes, see the answer to question 1.15 above.

4 Patent Term Extension

4.1 Can the term of a patent be extended and if so (i) on what grounds and (ii) for how long?

No, but a form of "extension" is available in EU Member States in respect of patents which cover an authorised medicinal or plant protection product, called a Supplementary Protection Certificate (SPC). The intent of the EU SPC Regulation is to reward investment in approval of a medicinal or plant protection product and SPCs are obtained in each country by filing an application with the relevant Patent Office within six months of the grant of the first authorisation of the product in that country. The scope of protection of an SPC is limited to the product as authorised and it takes effect upon expiry of the "basic" patent covering the product for a maximum term of five years or 15 years from the authorisation of the product, whichever is the earlier.

5 Patent Prosecution and Opposition

5.1 Are all types of subject matter patentable and if not what types are excluded?

Yes, in accordance with its obligations under the European Patent

Convention (EPC) and the WTO TRIPS Agreement, the UK Patents Act allows patents for all forms of technology. However methods of performing a mental act, playing a game or doing business and programs for computers are excluded; as are inventions the commercial exploitation of which would be contrary to public policy or morality.

5.2 Is there a duty to the Patent Office to disclose prejudicial prior disclosures or documents? If so, what are the consequences of failure to comply with the duty?

No, there is not. However, certain statements by the Court of Justice of the European Union in Case C-457/10P (*AstraZeneca*) make it clear that a patent owner in a dominant position in the market is under an obligation (under competition law) to act transparently before the Patent Office – in that case the penalty was the imposition of a fine. The European Patent Office requires an applicant for a patent to provide the results of any official search carried out on any priority application (other than one made in Japan, the UK or the US or one for which the European Patent Office drew up the search report), but there are no immediate legal consequences for failure to do so save, perhaps, that an applicant in a dominant position is now clearly under a duty to disclose such prior art given the *AstraZeneca* decision.

5.3 May the grant of a patent by the Patent Office be opposed by a third party and if so when can this be done?

No, the only way of doing this post-grant in the UK is to seek revocation. However the grant of a European Patent which designates the UK may be opposed at the European Patent Office.

5.4 Is there a right of appeal from a decision of the Patent Office and if so to whom?

Yes, an appeal lies to the Patents Court.

5.5 How are disputes over entitlement to priority and ownership of the invention resolved?

An application for a determination as to entitlement may be made before, or up to two years from, grant of a patent to the UK Intellectual Property Office. The UKIPO may refer the application to the Patents Court if the issues can be more properly determined there (where the rules on disclosure and evidence permit better examination of factually contested cases). Issues as to entitlement to priority are normally dealt with *ex parte* during the prosecution of the patent application, or *inter partes* in revocation proceedings.

5.6 Is there a "grace period" in your country and if so how long is it?

Under the European Patent Convention, and correspondingly in the UK under section 2(4) of the Patents Act 1977, there are certain limited exceptions which remove from the "state of the art" material which would otherwise form part of it. In the UK, the following matter disclosed during the six months prior to filing is so excluded: (a) a matter which is disclosed due to, or disclosed in consequence of, the matter having been obtained unlawfully or in breach of confidence by any person, which is directly or indirectly derived from the inventor; and (b) a matter which is disclosed due to, or disclosed as a consequence of, the inventor displaying the invention at a designated "international exhibition". In the latter case the applicant must, to benefit from the "grace period", file a statement and evidence relating to the disclosure at the international exhibition.

5.7 What is the term of a patent?

The term is 20 years from filing.

6 Border Control Measures

6.1 Is there any mechanism for seizing or preventing the importation of infringing products and if so how quickly are such measures resolved?

Yes, the EU Regulation concerning customs measures against goods suspected of infringing IP rights may be used to seize goods which infringe a patent or an SPC from entering the UK from outside the EU. An application to HM Revenue & Customs should be made at least 30 working days before the expected date of importation, with sufficient identification of the goods and the patented subject matter and an undertaking to pay all the liabilities and costs of the seizure. Upon seizure a notice is provided to the patent owner, who must apply to the court within 10 working days for an order for the further detention (or destruction) of the goods.

7 Antitrust Law and Inequitable Conduct

7.1 Can antitrust law be deployed to prevent relief for patent infringement being granted?

Yes, although a competition law defence has never succeeded in a patent action.

7.2 What limitations are put on patent licensing due to antitrust law?

See the answer to question 3.1 above.

8 Current Developments

8.1 What have been the significant developments in relation to patents in the last year?

Two decisions have dealt with issues arising on a cross-undertaking in damages given as a pre-requisite to the grant of an interim injunction.

In *Laboratoires Servier v Apotex Inc [2014] UKSC 55*, Servier argued it was against public policy for Apotex to recover damages in respect of sales of a product the manufacture of the active ingredient of which in Canada would have been "turpitude" as an infringement of the equivalent Canadian patent. The Supreme Court dismissed Servier's appeal based on this 'illegality defence'. "Turpitude" meant a criminal act or quasi-criminal act because only acts in these categories engage the public interest and it is the public interest which underlies the illegality defence. Patent infringement, being a tort or civil wrong, offended against private interests rather than the public interest. The only relevant interest affected was that of the

patentee and that was sufficiently vindicated by the availability for damages for the infringement in Canada. There was no public policy which justified the forfeiture of Apotex's right to be compensated in the UK. Cross-undertakings in damages were however supported by public policy in the UK.

In AstraZeneca AB & Anor v KRKA, d.d Novo Mesto and Consilient Health Limited the Court of Appeal upheld an award to the defendants of £27 million on an inquiry as to damages suffered as a result of an interim injunction. The Court of Appeal made it clear that a claimant who obtains interim relief can expect a liberal assessment of damages under any cross-undertaking if it is unsuccessful in its substantive claim. NHS Medicine Managers who gave evidence about switching were held to be well placed to assist the court as to how both they and GPs would have been likely to react to the launch of the generic product. The NHS has also been increasingly represented in patent proceedings for example involving second medical use patents. In Warner-Lambert v Actavis Respondent NHS Commissioning Board Interested parties: Teva, Generics UK, Dr Reddy's Laboratories, Consilient Health, Sandoz, Department of Health, [2015] EWHC 485, Warner-Lambert marketed a prescription-only drug for three different indications under a single registered trade mark. Patent protection for the drug had expired but Warner-Lambert also owned a second medical use patent for pain relief, which was one of the three indications. Actavis applied for a marketing authorisation for a generic version of the drug limited to the other two indications. Warner-Lambert sued for patent infringement and applied for an interim injunction requiring Actavis to take specific actions to prevent its generic version of the drug being dispensed for patients who had been prescribed the drug for the patented indication. It was agreed that the best solution to the problem of how to prevent the drug being dispensed for pain was to try to ensure that, when doctors prescribed it for pain, they always did so only by reference to the brand name. Warner-Lambert made an unopposed application for an order that NHS England should issue guidance to this effect and the High Court ordered NHS England to issue guidance along those lines. This novel form of order was held to be proportionate, did not create barriers to trade and also contained appropriate safeguards in compliance with Article 3 of the Enforcement Directive.

Another interesting development occurred in *Nampak Plastics Europe Ltd v Alpla UK Ltd* where summary judgment was granted to the claimant in a patent action for a declaration of non-infringement. Summary judgment is a procedure by which all or part of a case can be disposed of without a trial where claim or a defence to a claim has no real prospect of success. It has seldom succeeded in patent infringement actions because in order to determine infringement, the court needs to construe the claims as they would be understood by the skilled person in the art and for that purpose normally needs expert evidence on the common general knowledge and the skilled person's understanding of the words in the claims. The Court of Appeal agreed with the judge that in this case the patent claims contained no terms of art and the technology was sufficiently simple for there to be no need to call expert evidence.

8.2 Are there any significant developments expected in the next year?

Since the mid-1990s, the Patents Court has aimed to provide litigants with a jurisdiction in which they can expect actions to be

brought to trial within 12 months of commencement. Recently the time elapsing between commencement of the claim and the trial has been increasing. Various steps have therefore been taken to ensure that the speed within which cases can be expected to come to trial, which is recognised as one of the advantages of the UK as a jurisdiction, is not lost.

In January 2015, Mr Justice Arnold, the senior of the two Patents Court Judges, announced that to achieve the long standing aim of patent actions being brought to trial (where possible) within 12 months of the claim being issued, a number of steps would be taken including: (1) the use of more Deputy High Court Judges to hear patent cases; and (2) greater use of the court's case and costs management powers to set limits on the length of trials and at the same time allocate fixed periods of time for the parties to crossexamine witnesses and argue their case orally at trials. A third Patents Court Judge will also take up his appointment in the next year.

Further clarification of the law relating to infringement of second medical use patents, particularly on the issue of subjective intention, can be expected following full trial in *Warner-Lambert v Actavis*. In the proceedings to date for interim relief the Court of Appeal considered that subjective intent was not necessary for Swiss-form claims. The skilled person would understand that the patentee was using the word "for" in the claim to require that the manufacturer knew or could reasonably foresee the ultimate intentional use for pain (the patented indication), not that the manufacturer had that specific intention or desire himself. The issue of infringement, and if so what remedy is appropriate, remains to be considered at full trial. Having refused interim relief, the Court of Appeal did not have to decide the issue of subjective intent at this stage, and so arguably its comments and guidance in that regard were *obiter*. The issue may ultimately have to be considered by the Supreme Court.

8.3 Are there any general practice or enforcement trends that have become apparent in England and Wales over the last year or so?

Fixed-length trials have been trialled (as a pilot scheme for some cases) in the Patents Court from 1 May 2014. A fixed-length trial is required to be completed within the period allocated to it. As a necessary corollary to the imposition of a trial of fixed length, the Patent Judges employ their enhanced case management powers, introduced on 1 April 2013 as part of the Jackson Reforms to civil procedure, in order to ration the parties' use of the court time and resources. Where fixed-end trials occur, judgment will be given very quickly, within a few days.

We expect increased use of docketing, assigning the same judge to hear all case management hearings, particularly in complex cases.

There has been an increase in the numbers of claims brought before the IPEC, but no corresponding reduction in claims brought in the Patents Court. IPEC reforms have therefore increased the overall number of litigants able to enforce their rights in the UK. The possibility of transfer from the High Court to IPEC and streamlined procedure of the IPEC has been influential on the implementation of case management reforms in the Patents Court. The IPEC was also the model used for the procedural rules of the Unified Patent Court.



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