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1 Patent Enforcement

1.1 Before what tribunals can a patent be enforced against an infringer? Is there a choice between tribunals and what would influence a claimant's choice?

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), 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-sized 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 the IPEC are conducted before specialist patents judges. Infringement claims may, alternatively, be brought in the UK Intellectual Property Office (UKIPO), but only by agreement of the parties. Furthermore, injunctions are not available in the UKIPO; therefore, the jurisdiction is little used.

1.2 What has to be done to commence proceedings, what court fees have to be paid and how long does it generally take for proceedings to reach trial from commencement?

Proceedings are commenced: in the Patents Court by filing with the court a Claim Form with brief Particulars of Claim; and in the IPEC by filing with the court a Claim Form with Particulars of Claim, setting out all the facts and arguments relied upon in a concise manner. Electronic filing became mandatory on 25 April 2017 and it is no longer possible to issue claims, applications or file documents on paper.

For infringement actions claiming damages above £10,000, or unspecified damages, the court fee is based on 5% of the value of the claim, subject to a maximum of £10,000. Therefore, if the claim is for more than £200,000, the court fee is £10,000.

Where the claim is for a non-monetary remedy, such as a revocation action or a claim for injunctive relief with no claim for damages, there is a fixed fee of £480. However, where a claim for injunctive relief includes a claim for unlimited damages, then the fee is £10,000.

The aim of the Patents Court and the IPEC is to bring cases to trial within 12 months of commencement, and steps have been taken to ensure that this target is met.

1.3 Can a party be compelled to disclose relevant documents or materials to its adversary either before or after commencing proceedings, and if so, how?

Yes. Before the Jackson Reforms to civil procedure, 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. 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 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. The court may decline to order disclosure, for example where the only issue is obviousness, if it considers such limitation on disclosure to be in accordance with the overriding objective to deal with cases justly and at proportionate cost (*Positec Power Tools (Europe) Ltd and others v Husqvarna AB* 2016).

In the IPEC, a party does not have an automatic right to any disclosure. Instead, disclosure is dealt with at the case management conference on an issue-by-issue basis in accordance with the IPEC's costs-benefit analysis, balancing the likely probative value of the documents against the cost or difficulty of the search.

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.

Pre-action disclosure is possible. For example, in one case, it was ordered in respect of a patentee's licence agreements, so as to allow

a potential defendant to quantify the value of a patent infringement claim and decide whether to litigate or settle. The patentee had repeatedly relied on the fact that others had taken licences in its efforts to persuade the alleged infringer to take a licence under the patent. (*Big Bus v Ticketogo* 2015.)

1.4 What are the steps each party must take pre-trial? Is any technical evidence produced, and if so, how?

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 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.

The pre-trial procedure in the IPEC, in addition to the features identified above, 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.

Before the trial, 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 (if any), (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 noted, (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. Increasingly the defendant's advocate may also give an opening speech. The claimant's advocate then calls the claimant's experts and witnesses to briefly confirm their written evidence, after which they are submitted to cross-examination 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 the 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. Following this, the claimant's advocate 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 if any of the witnesses and experts) and set the timetable, in order 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 that 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; therefore, 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, in the Patents Court, 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. Trials in the IPEC are limited to two days. 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 within four to eight weeks after the end of the trial.

1.7 Are judgments made available to the public? If not as a matter of course, can third parties request copies of the judgment?

Copies of reserved judgments in writing are generally supplied in confidence to the parties a few days before handing down. The judgment becomes public and may be freely disclosed when it

is handed down by the court, subject to any order to preserve the confidentiality of any material contained in the judgment. Judgments with parts redacted may be issued in such circumstances. Third parties can attend hearings when judgments are handed down and/or request copies of judgments from the judges' clerks.

The Royal Courts of Justice currently provide copies of significant judgments to the British and Irish Legal Information Institute (BAILII), for publication on the bailii.org website.

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

Yes to both. In the Patents Court, three of the designated judges have a science background, and are normally allocated to cases with a higher technical difficulty rating. 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.

1.9 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.

(iii) Declaratory proceedings fall into two categories: statutory 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.

1.10 If declarations are available, 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 European Telecommunications Standards Institute (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.

In *Fujifilm v AbbVie*, the Court of Appeal confirmed the availability of "Arrow declarations" (named after the case of *Arrow Generics v Merck* where they were first granted in 2007). Arrow declarations are a discretionary remedy which may be used to clear the way in cases where, because the patents potentially blocking a new product or process are not yet granted, a declaration of non-infringement would not be available. Such declarations provide that the intended product or process was known or obvious at the priority date of the patent application of concern. As and when the patent is granted, the Arrow declaration will operate as a "Gillette" defence to any future infringement action: if the product or process is known or obvious, then so also is the patent it is alleged to infringe.

1.11 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, or offer to supply, of 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.

1.12 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.

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

Yes. Courts in the UK apply Article 69 of the European Patent Convention and the Protocol on its Interpretation by giving patent claims a "purposive" interpretation, i.e. 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. The UK courts' sole focus on claim construction to protect equivalents was, however, brought to an end by the recent decision of the UK Supreme Court in *Actavis v Eli Lilly*. The Supreme Court held that an item which did not infringe a claim as a matter of normal interpretation may nonetheless infringe because it varies from the invention in a way which is immaterial and provided guidance as to the circumstances in which a variation will be considered "immaterial".

1.14 Can a defence of patent invalidity be raised, and if so, how? Are there restrictions on such a defence e.g. where there is a pending opposition?

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.

A Claim or Counterclaim for revocation may be raised regardless of whether there is a pending opposition. See the answer to question 1.15 for the factors weighed by the court when deciding whether or not to stay an infringement action, including any Counterclaim with Grounds of Invalidity, pending an opposition.

Since October 2014, the UK Intellectual Property Office (UKIPO) has also had the power to revoke a patent following an unfavourable validity opinion relating to novelty or inventive step requested by a third party. This power to revoke is exercised only in "clear-cut" cases. In February 2016, in a case where the patentee did not contest the negative opinion, the UKIPO issued a decision revoking a patent for the first time.

1.15 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 post-grant amendment to the claims that should not have been allowed, and (v) the patent was granted to someone who was not entitled to it.

1.16 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 issued 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 other 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 opposition proceedings is to be given less weight than previously.

1.17 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 is 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.

1.18 Are (i) preliminary, and (ii) final injunctions available, and if so, on what basis in each case? Is there a requirement for a bond?

(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.

(ii) Final injunctions are generally granted if the claimant 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.

1.19 On what basis are damages or an account of profits assessed?

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 known as "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 which 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.

1.20 How are orders of the court enforced (whether they be for an injunction, an award of damages or for any other relief)?

Damages awards or other financial orders of the court may be enforced in two ways: through bailiffs as officers of the court seizing the assets of the non-compliant party and auctioning them off to meet the order; or by the filing of a statutory demand against a company resulting in the winding up of the company. Orders to freeze bank accounts and for sequestration of a judgment debtor's assets are also possible in appropriate cases.

Failure to comply with an order made by a court to do or refrain from doing something may result in proceedings being brought for contempt of court. The penalties for being found to be in contempt of court include a custodial sentence of up to two years and/or an unlimited fine or seizure of assets. In the case of contempt of court by a company, the court can order, in certain circumstances, the committal into custody of a director or other company officer. Given the serious nature of the penalties, contempt is assessed using the criminal standard of proof, i.e. beyond reasonable doubt, as opposed to on the balance of probabilities for civil matters.

1.21 What other form of relief can be obtained for patent infringement? Would the tribunal consider granting cross-border relief?

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), and/or (iii) an award of costs.

In a case where validity was not in issue, the English court granted declarations of non-infringement in respect of the foreign counterparts of a UK European patent, a decision which has been upheld by the Court of Appeal. In most cases, however, where validity is raised as a counterclaim, there can be no cross-border relief in relation to a European patent because the other countries designated have exclusive jurisdiction over patent validity.

1.22 How common is settlement of infringement proceedings prior to trial?

Many patent actions do settle before trial, although this is less likely to happen, for example, in the case of major pharmaceutical patent litigation, where the stakes for both parties are very high. Mediation or other forms of ADR aimed at settling the dispute before trial are actively encouraged by the courts as part of their increased involvement in case and costs management.

1.23 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.

1.24 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.

The Court of Appeal confirmed in *Teva v Boehringer Ingelheim* that applications for permission to appeal in patent cases should be treated no differently to any other case and in particular should not be granted more easily than in other cases because of the complex technical subject matter.

1.25 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 £550,000 to £850,000 for the Patents Court (much lower for the IPEC) depending on such matters as the number of patents/claims in dispute, the number and nature of the invalidity attacks, and whether more than one expert is required to give evidence at the trial. In more complicated actions involving extensive disclosure of documents or experiments, 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 1.4. In the Patents Court, following the recent introduction of wide-ranging procedural reforms, 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 which are the subject of that order. Where costs budgets have been employed, the winning party is likely to recover 80–90% of those costs.

1.26 For jurisdictions within the European Union: What steps are being taken in your jurisdiction towards ratifying the Agreement on a Unified Patent Court, implementing the Unitary Patent Regulation (EU Regulation No. 1257/2012) and preparing for the unitary patent package? For jurisdictions outside of the European Union: Are there any mutual recognition of judgments arrangements relating to patents, whether formal or informal, that apply in your jurisdiction?

Following the UK's referendum vote on 23 June 2016 to leave the European Union, on 29 March 2017 the UK initiated the two-year exit procedure envisaged by Article 50 of the Treaty of the European Union. The UK is expected to enter a negotiation period during which laws will be amended and enacted and international agreements may be negotiated. Due to the required notice period, the actual exit date will not be before March 2019. The UK, along with France and Germany, is required to ratify the Unified Patent Court (UPC) Agreement before it comes into force. The "Brexit" vote has inevitably delayed the implementation of the UPC system, which will not become operational in December 2017 as originally planned. However, the UK indicated in November 2016 that it intends to ratify the UPC Agreement. The necessary secondary legislation to give the UPC its legal personality in the UK, the UPC (Immunities and Privileges) Order 2017, has been laid before the Westminster Parliament (a similar instrument needs to be laid before the Scottish Parliament) and, once they have passed, the UK will be able formally to ratify the UPC Agreement.

Absent renegotiation of the UPC Agreement, when it exits the EU, the UK, whilst it will still be a signatory to the European Patent Convention and a European (UK) patent could still be obtained via the EPC system, will not be able to participate in the new UPC system, which only applies to participating EU Member States. Since, for the majority of potential users of the UPC, the system would be less valuable without the participation of the UK, it is hoped that the considerable goodwill of all those involved in the project for many decades will overcome any political obstacles preventing amendments or further agreements to facilitate the UK's continuing involvement.

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 (therefore, *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/invalidity 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 EPC, 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, until the UK exits the 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 1.17 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. The UK's exit from the EU means that legislation will be required to enable SPC protection to continue to apply in the UK. The exact form of the new law will depend on whether the UK stays in the European Economic Area (EEA), but some form of SPC protection will probably be established. Transitional provisions will also need to be established for SPCs in force at the time of exit, in order to ensure that they continue to have effect in the UK.

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.

The UK's exit from the EU does not affect the ability to obtain UK patent protection via the EPC. The UK Patents Act has implemented various EU Directives over the years, for example the Biotech Directive and the "Bolar" (experimental use exemption) Directive, but these implementations will not necessarily be repealed when the UK leaves the EU.

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 jurisdiction, and if so, how long is it?

Under the EPC, 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 with 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. Following the departure of the UK from the EU, however, customs seizure remedies across the EU will cease to be available to IP owners. Depending on any agreement which may be negotiated, it will probably be necessary to file a request for border seizure measures with both the European customs authorities and the UK's Border Force. The latter has a separate unit under the Trade Marks Act 1994 to seize counterfeit 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?

The three specialist patents judges assigned to patent actions with a high technical complexity rating continue to be Mr. Justice Arnold, Mr. Justice Birss and Mr. Justice Henry Carr. Seven other judges of the Patents Court may hear less technically complex patent cases, as well as a continuing number of Deputy High Court judges with patent expertise including Daniel Alexander QC, Iain Purvis QC, Roger Wyand QC, John Baldwin QC, Douglas Campbell QC and HHJ Richard Hacon (who also presides over the Intellectual Property Enterprise Court).

The Court of Appeal's confirmation in *Fujifilm v AbbVie* of the availability of "Arrow declarations" (see response to question 1.10) was a significant development. Arrow declarations have since been granted following full trial of the action. Special reasons supporting the grant of the declarations included: AbbVie's conduct of threatening infringement but abandoning proceedings at the last moment (in order to shield its patent portfolio from scrutiny); the amount of money at stake in terms of investment in clinical trials and potential damages if Fujifilm's intended products were launched at risk; and the need for commercial certainty, having regard to AbbVie's threats to sue for infringement throughout the world.

After the technical trials in *Unwired Planet v Huawei*, the court held a separate trial to determine the issue of a FRAND royalty rate (on fair, reasonable and non-discriminatory terms) over a worldwide portfolio of patents. A further remedies hearing considered the correct form of a final injunction in the case of patents subject to a FRAND undertaking when the court has settled a FRAND licence but the defendant has not entered into it. It held that a FRAND injunction should be granted to restrain infringement of the relevant patents with a proviso that it will cease to have effect if the defendant enters into the FRAND licence. The court noted that the grant or refusal of an injunction is an exercise of the court's discretion although when infringement has been established and there is a threat of infringement in the future, an injunction will normally be granted. Although the practical effect of undertakings can be the same as an injunction, where the claimant has been forced to come to court, an offer of undertakings after judgment is likely to be regarded as too late.

There have been significant, but as yet inconclusive, developments in relation to the infringement of second medical use patents in two long-running disputes involving the drugs pregabalin and pemetrexed, in particular the extent to which any relevant intention or knowledge is negatived where the manufacturer has taken all reasonable steps within his power to prevent certain consequences occurring.

The pemetrexed litigation (*Actavis v Eli Lilly)* concerned Eli Lilly's patent with Swiss-type claims to the use of pemetrexed disodium for the treatment of cancer. The question was whether preparations of pemetrexed salts would be reconstituted with saline so creating the patented solution pemetrexed disodium. The Court of Appeal considered that Eli Lilly's patent was not directly infringed by Actavis's pemetrexed products but that indirect infringement would occur as a result of the reconstitution with saline by healthcare practitioners, notwithstanding instructions to reconstitute with dextrose. However the Supreme Court recently reversed the Court of Appeal and found that the Actavis products directly infringed. It also found *obiter* there would have been indirect infringement. The decision is an extremely important one for the law of patent infringement in the UK. The Supreme Court held that an item which did not infringe a claim as a matter of normal interpretation may nonetheless infringe because it varies from the invention in a way which is immaterial. In so doing, it reformulated the law as to the circumstances in which a variation will be considered immaterial, moving away from the previous focus in the UK on claim construction to protect equivalents.

The pregabalin litigation (*Warner-Lambert v Actavis*) is also concerned with issues of intention and knowledge in the context of second medical use patents. The judge found that Warner-Lambert's patent for the use of pregabalin in the treatment of pain was invalid and in any event not infringed by Actavis' skinny label pregabalin product. The Court of Appeal upheld the judge's findings on the validity of the patent but disagreed with him, *obiter*, on issues concerning the construction and infringement of Swiss type claims (*Warner-Lambert Company LLC v Generics (UK) Ltd (t/a Mylan) & Ors*). For the Court of Appeal, the issue on direct infringement was whether Actavis knew or could reasonably foresee that at least some of the prescriptions written generically for pregabalin to treat pain (the patented indication) would in fact be fulfilled with its product. On indirect infringement the Court of Appeal considered that the process of preparing the composition can continue through any packing step performed by the manufacturer and includes the labelling step performed by the pharmacist. Such acts, performed downstream of manufacture, could therefore be regarded as relevant acts of preparation if done with the relevant intention. Various issues are currently under appeal and a judgment of the Court of Appeal is expected.

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

The UK is expected to ratify the UPC Agreement in the course of the next year. Assuming Germany also ratifies, although the exact timetable for the start of the operation of the UPC has not yet been set, if there are no further obstacles, it is possible the sunrise period for opt-outs could start on 1 January 2018 and the court might open for business on 1 March 2018.

It is likely that during the next year there will be negotiations about the exact terms of the UK's formal departure from the EU. The UK

Government's White Paper, "Legislating for the United Kingdom's withdrawal from the European Union" proposes that the Repeal Bill will ensure so far as possible that the same rules and laws apply after the UK leaves the EU as did before, unless and until domestic law is changed by legislators in the UK. This will include converting directly applicable EU regulations into UK law and preserving laws made in the UK to implement EU directives. The Bill will also provide that, for the sake of certainty, historic CJEU case law should be given the same binding precedent status in UK courts as Supreme Court decisions.

As noted in the answer to question 8.1, the Court of Appeal is expected to rule on the pregabalin litigation.

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

The Practice Statement of December 2015 requiring patent cases to be brought to trial within 12 months where possible remains in force and is an influential trend in practice. Judges have, for example, refused to allow jurisdictional challenges and strike-out applications to adjourn the listing of the trial date. Split trials have also been ordered in multiple patent actions in order to ensure the trial takes place within the 12 month guideline.

In *EMGS v PMS*, the court gave general guidance about whether the court should sit with a scientific adviser. Patents judges with a technical background can generally handle complex cases assisted by a technical primer, the expert witnesses and the parties' legal teams. However, where a case involves a difficult area of science, the parties may arrange for the judge to have a non-controversial introductory course. Transparency is maintained by settling the instructions to the adviser in advance and by giving any written materials produced by the scientific adviser for the judge to the parties after the introductory course has taken place.

In the same case, the court gave guidance in relation to use of experiments. Where computer simulations or computer modelling are involved, the input data and computer software must be disclosed to the other party for the purpose of witnessed repeat experiments. The court also emphasised that it must be clearly explained what facts the experiments were supposed to prove and their relevance to the case.

In *MSD v Shionogi*, the court gave guidance on cross-examination of expert witnesses in patent cases emphasising that courts should be cautious in criticising experts on the basis of omissions from their reports since this may result from incorrect instructions. *ASE v Rapiscan* also dealt with the importance of correctly instructing expert witnesses, in particular the order in which they are shown the relevant documents in order to avoid being tainted with hindsight. Experts should be asked to consider common general knowledge and the prior art before they are shown the patent. The court preferred asking experts to consider obviousness before showing them the patent so that they can consider whether or not differences between the prior art and the invention are obvious steps free from knowledge of the patent.

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