International Comparative Legal Guides

Patents 2021

A practical cross-border insight into patent law

11th Edition

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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 Can the parties be required to undertake mediation before commencing court proceedings? Is mediation or arbitration a commonly used alternative to court proceedings?

Mediation or other forms of Alternative Dispute Resolution (ADR) are not compulsory but encouraged by the courts as part of their increased involvement in case and costs management. Unreasonable refusal to mediate or engage in ADR may incur costs sanctions, but only if there is considered to be a realistic prospect of success. ADR is becoming more common either as an alternative or adjunct to court proceedings.

1.3 Who is permitted to represent parties to a patent dispute in court?

Most substantial patent litigation in the UK is conducted by a team of solicitors and barristers. Although barristers, qualified solicitor-advocates and patent attorneys certified as IP Patent Litigators may undertake advocacy in the Patents Court, in substantial cases the oral advocacy at trial is normally conducted by barristers. In the IPEC, in addition to the rules on who can represent litigants before the Patents Court, solicitors and patent attorneys have rights of audience and can conduct the oral advocacy.

1.4 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 infringements cases, Particulars of Infringement. In contrast, in the IPEC, the Particulars of Claim and Particulars of Infringement must be fuller, 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 £528. 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.

1.5 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. A mandatory Disclosure Pilot Scheme in the Business and Property Courts (B&PCs) which includes the Patents Court was introduced from 1 January 2019.

Initial Disclosure of key/limited documents which are relied on by the disclosing party and are necessary for other parties to understand the case they have to meet must be given with statements of case. A search should not be required for Initial Disclosure, although one may be undertaken. After close of statements of case, and before the Case Management Conference, the parties are required to discuss and jointly complete a Disclosure

Review Document (DRD) (which replaces the existing Electronic Disclosure Questionnaire).

At the Case Management Conference, the court considers, by reference to the DRD, which of five "Extended Disclosure" Models (Models A to E) is to apply to which issue (or to all issues). The models range from an order for no disclosure in relation to a particular issue, through to the widest form of disclosure, requiring the production of documents which may lead to a train of enquiry.

Unless the court orders otherwise, no disclosure of the following classes of documents will be ordered: (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 will be proactive in directing which is the appropriate Model and need not accept without question the Model proposed by the parties. 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 v Husqvarna* [2016]). However, in appropriate cases disclosure will be ordered under the Disclosure Pilot Scheme. Issue-based disclosure was ordered in *Merck Sharp & Dohme v Wyeth* [2019] where it was held proportionate search should be made for and disclosure given of laboratory notebooks, internal reports, e-mails, meeting minutes or presentations created, modified or received by the named inventors which provided information relating to the conclusion in the presentation pleaded in the defence. In *Akebia v FibroGen* [2019], although the court refused to increase the scope further, the parties agreed wide disclosure dealing with test data on the functional and therapeutic properties of molecules in the context of an allegation of insufficiency.

The Disclosure Pilot Scheme does not operate in relation to IPEC proceedings, nor to proceedings within the Shorter and Flexible Trial Schemes.

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.

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].)

1.6 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.

1.7 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 1.6, 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.

1.8 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 1.7, 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.

1.9 Is there any alternative shorter, flexible or streamlined procedure available? If so, what are the criteria for eligibility and what is the impact on procedure and overall timing to trial?

The Shorter Trial Scheme (STS) was adopted permanently in October 2018 after a successful pilot scheme. If a case is allocated to the STS it will be managed by docketed judges to provide greater continuity, efficiency and judicial understanding of and control over the management of the case. The trial should be fixed for a date not more than eight months after the CMC and the maximum length of trial is four days including reading time. The trial, which will be before the same docketed judge, should therefore take place within about 10 months of issue of proceedings, and judgment will be handed down within six weeks thereafter. The main advantage of the STS is therefore its speed compared to normal High Court proceedings, and it is similar to the IPEC in its limitation to specific disclosure only. Costs budgets do not apply to cases in the STS, unless the parties agree otherwise, with costs instead being summarily assessed. Patent judges are keen to promote the scheme and willing to refuse applications to transfer out where cases are deemed suitable. Where, however, complex patent and design cases are likely to take longer than four days or require extensive disclosure, there may be a transfer out.

The Flexible Trials Scheme (FTS), which was also adopted permanently in October 2018, allows parties by agreement to adapt trial procedure to suit their particular case. Trial procedure encompasses pre-trial procedure, witness and expert evidence, and submissions at trial. The FTS is designed to encourage parties to limit disclosure and confine oral evidence at trial to the minimum necessary, and reduce costs and time for trial, enabling earlier trial dates. A default FTS procedure is provided which applies where parties adopt the procedure, unless the parties agree or the court orders otherwise. The key aim is flexibility for the parties to agree a procedure appropriate to their case, although the Court retains ultimate control over the procedure adopted.

A further alternative option is that either party may apply to the Court for an order that the action proceed by way of a "streamlined procedure". The most appropriate time to make such an application is at the CMC.

If an action proceeds by way of the streamlined procedure, then, except as otherwise ordered:

- all factual and expert evidence is in writing;
- there is no requirement to give disclosure of documents;
- there are no experiments;
- cross-examination is only permitted on those topics where it is necessary;
- the total duration of the trial is fixed and will not normally be for more than one day; and
- the trial date is normally fixed for about six months after the Case Management Conference.

The streamlined procedure is designed to cater for technically simple cases for which the Court's evidence gathering procedures is not necessary for a satisfactory determination.

1.10 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.

1.11 Are courts obliged to follow precedents from previous similar cases as a matter of binding or persuasive authority? Are decisions of any other jurisdictions of persuasive authority?

In the common law jurisdiction of England and Wales, previous decisions of higher courts are binding on lower courts unless

there are reasonable grounds for distinguishing the case on its facts. Only the *ratio decidendi* or essential element of the judgment creates binding precedent, as opposed to *obiter dicta* which do not have binding authority.

Decisions of the courts of major European and Commonwealth patent jurisdictions and of the European Patent Office, particularly the Enlarged Board of Appeal, are not binding but of persuasive authority.

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

Yes to both. In the Patents Court, there are designated judges or deputy judges who 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.

1.13 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.

1.14 If declarations are available, can they (i) address non-infringement, and/or (ii) claim coverage over a technical standard or hypothetical activity?

(i) Yes, as indicated above (question 1.13).

(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* [2017], the Court of Appeal confirmed the availability of "Arrow declarations" (named after the case of *Arrow Generics v Merck* [2007] 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.

1.15 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.

1.16 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.

1.17 Does the scope of protection of a patent claim extend to non-literal equivalents (a) in the context of challenges to validity, and (b) in relation to infringement?

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 decision of the UK Supreme Court in *Actavis v Eli Lilly* in 2017. 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".

Actavis also raised the question of whether there can be anticipation by equivalence. Although it was rejected in *Generics v Yeda Research and Development* [2017], the question has yet to be decided by the Court of Appeal.

1.18 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? Are the issues of validity and infringement heard in the same proceedings or are they bifurcated?

Invalidity 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 1.21 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.

In the UK, validity and infringement are dealt with in the same proceedings and not bifurcated.

Since October 2014, the 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.

1.19 Is it a defence to infringement by equivalence that the equivalent would have lacked novelty or inventive step over the prior art at the priority date of the patent (the "*Formstein* defence")?

There is no such defence in English law. However, in *Technetix v Teleste* [2019], following *Actavis v Eli Lilly* (see answer to question 1.17), the IPEC considered the case on the hypothesis that such a defence existed. The Formstein defence was fully pleaded and argued at trial and, if it had existed, would have succeeded. Whether such a defence exists in UK law after *Actavis* is a question for the Court of Appeal and ultimately the Supreme Court.

1.20 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.

1.21 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.

1.22 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.

1.23 (a) Are preliminary injunctions available on (i) an *ex parte* basis, or (ii) an *inter partes* basis? In each case, what is the basis on which they are granted and is there a requirement for a bond? Is it possible to file protective letters with the court to protect against *ex parte* injunctions? (b) Are final injunctions available? (c) is a public interest defence available to prevent the grant of injunctions where the infringed patent is for a life-saving drug or medical device?

a) 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. Only in very exceptional cases is an injunction granted on an *ex parte* basis and then only where the claimant can show that the matter is so urgent that the defendant may not be notified or where there is a real concern that the defendant may dispose of evidence.

Interim injunctions are unusual in patent cases and are, in practice, restricted to pharmaceutical cases where a defendant proposes to introduce a generic product and where the claimant can show that there will be irreparable damage as a result of irreversible price erosion. 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. Where the claimant seeks an interim injunction which would affect dealings in a pharmaceutical product or medical device purchased by the National Health Service (NHS), the Court will consider whether it should give such an undertaking in favour of the NHS.

Protective letters are not available in the UK.

(b) Final injunctions are 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 2004/48/EC 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.

(c) A general injunction to restrain future infringements is the normal remedy for patent infringement and the onus is on the defendant to give reasons why such an injunction should not be granted. The public interest, such as the impact on third parties, is a relevant consideration which might justify refusal of, or a carve-out from, an injunction, and an award of damages *in lieu*. In *Evalve v Edwards Lifesciences* [2020] the court noted that Parliament (rather than the courts) should examine conflicting public issues and draw the appropriate balance, and held that the court's jurisdiction to refuse or qualify a patent injunction on public interest grounds should be used sparingly and in limited circumstances. In the context of a potentially life-saving medical device, what was required for the public interest was sufficient objective evidence that there were patients who ought not to be treated using the patented product, but who could, in the reasonable opinion of doctors, be treated using the defendant's product. In other words, there must be objective evidence that lives would be lost or at risk if an injunction were granted.

1.24 Are damages or an account of profits assessed with the issues of infringement/validity or separately? On what basis are damages or an account of profits assessed? Are punitive damages available?

In the UK, the quantum 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" or "an account of profits". 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 uncertainty 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.

1.25 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.

1.26 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.

1.27 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. See the answer to question 1.2 regarding mediation or other forms of ADR aimed at settling the dispute before trial which are actively encouraged by the courts as part of their increased involvement in case and costs management.

1.28 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.

1.29 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* [2016] 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.

1.30 What are the typical costs of proceedings to a 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 £600,000 to £1,000,000 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 1.6. 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 at least 80–90% of those costs.

1.31 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? Will your country host a local division of the UPC, or participate in a regional division? 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?

The UK Government ratified the UPC Agreement in 2018 and confirmed that it intended to explore staying in the UPC and unitary patent system following the UK's exit from the EU on 31 December 2020. However, on 4 March 2020 the UK announced that it would not be seeking involvement in the UPC or the unitary patent system, as participating in a court that applies EU law and is bound by the Court of Justice of the EU would be inconsistent with the UK's aims of becoming an

independent self-governing nation. On 20 July 2020, the UK took the next step and withdrew its ratification of the UPC Agreement with immediate effect. It explained that doing so ensured clarity regarding the UK's status in respect of the Agreement and would facilitate the orderly entry into force for the participating states. The UK will therefore take no further part in the UPC. 'British companies will still be able to use the system if and when it comes into operation, although the unitary patent will not cover the UK.

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 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 1.22 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.

After the UK's exit from the EU on 31 December 2020, the Withdrawal Agreement ensures that SPC applications pending at the end of the transition period will be examined under the current framework. Any SPC which is granted based on those applications will provide the same protection as existing SPCs. From 1 January 2021, an SPC can be applied for in the same way as before by submitting an application to the UK Intellectual Property Office.

SPCs that have already taken effect will remain in effect after 31 December 2020. SPCs granted but not yet in force will come into force at the end of the associated patent term as normal. SPCs filed after the end of the transition period will get the same term of protection as they would have if filed before, based on the first authorisation to place the product on the market in either the UK or the EEA.

As was the case before under EU law, an SPC can only be granted if the product is protected by a patent, and covered by a marketing authorisation in the Member State where SPC protection is being sought. There must therefore be a patent that is valid in the UK, and a marketing authorisation which allows the product to be sold on the UK market at the time the SPC is applied for. This includes authorisations granted by the UK's Medicines and Healthcare products Regulatory Agency, and any authorisations granted by the European Medicines Agency which have been converted into equivalent UK authorisations on 1 January 2021.

After the transition period, it will no longer be possible for UK courts to make references to the Court of Justice of the European Union (CJEU) for interpretation of the SPC legislation and other retained EU law. Judgments of the CJEU issued before 31 December 2020 will continue to apply to the retained EU law after the transition period. The amendments made by the Patents Regulations 2019 are written to have the same meaning as the original EU legislation, so that existing case law still applies.

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 Biotechnology 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.

5.8 Is double patenting allowed?

No, section 18(5) of the Patents Act 1977 provides that, where two or more UK national patent applications are for the same invention, and have the same priority date and the same applicant, then a patent may be refused for one or more of those applications. In addition, section 73(2) of the Patents Act 1977 provides that the UK Intellectual Property Office (UKIPO) may revoke a UK national patent if both a UK national patent and a European patent (designating the UK) have been granted for the same invention.

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. The European Commission's Notice to Stakeholders dated 4 June 2018 confirms that as of the withdrawal date of the UK from the EU, customs seizure measures previously granted by UK Customs will no longer be valid in the EU. In the case of customs measures filed through UK Customs, if a rights holder wishes to continue to have customs enforcement in the EU after the UK's withdrawal, it will need to file a new request with Customs in one of the other EU Member States before the date of withdrawal of the UK from the EU.

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.

7.3 In cases involving standard essential patents, are technical trials on patent validity and infringement heard separately from proceedings relating to the assessment of fair reasonable and non-discriminatory (FRAND) licences? Do courts grant FRAND injunctions, i.e. final injunctions against patent infringement unless and until defendants enter into a FRAND licence?

In the UK technical trials dealing with validity and infringement are heard separately from proceedings relating to FRAND licensing issues. In *Unwired Planet v Huawei* [2017] the High Court held that it had jurisdiction to award a licence rate for a global patent portfolio, and also to order an injunction in respect of unlicensed infringements for UK standard essential patents. In 2018, the decision was upheld on appeal to the Court of Appeal. The question of whether it is appropriate to require the taking of a global FRAND licence to avoid a UK injunction has been appealed to the Supreme Court and, as of July 2020, judgment is awaited.

8 Current Developments

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

Following the appointment of Lord Justices Arnold, Birss and Nugee to the Court of Appeal, and the sad early demise of Mr Justice Henry Carr, there are likely to be further judicial appointments to the Patents Court, as well as continuing increased use of Deputy High Court Judges.

The UK's decision, as a result of Brexit, not to participate in the Unified Patent Court is also a significant development with potential repercussions for the future of the UPC system as a whole as well as the UK. See answer to question 1.31.

In *Regeneron v Kymab* [2020] the Supreme Court upheld Kymab's appeal challenging Regeneron's patents covering Kymab's transgenic mouse. It was held that, where the teaching in a product patent enabled the skilled person to make only some, not all, of the types of product within the scope of the patent's claim, the patent was invalid for insufficiency, even where the invention would contribute to the utility of all the products in the range, if and when they could be made. Earlier UK decisions, influenced by the European Patent Office case law, had allowed broader claims in circumstances where products may all be produced using a principle that is of general application even if the patent does not disclose specifically how to make each type. This decision could therefore have a profound effect on the validity of many patents, particularly in the life sciences area.

There have also been two significant developments as a result of the COVID-19 pandemic. The first is that both the judiciary and practitioners in the UK Patents Court have acquired extensive expertise in conducting remote and partially remote (hybrid) court hearings which make the UK an attractive and cost-effective forum for international patent litigation, using similar protocols to those developed for use in international arbitration.

Secondly, in the context of COVID-19, the UK Government has indicated that it may if necessary avail itself of the Crown Use provisions (briefly outlined in the answer to question 1.22). Section 55(1) of the Patents Act 1977 allows a government department or any person authorised in writing by a government department to make use of patented inventions for the services of the Crown without the consent of the patent proprietor. This can include the production or supply of specified drugs and medicines. During periods of emergency, the definition of use for "services of the Crown" is widened (section 59), for example, to include the maintenance of supplies and services essential to the life of the community. This may make it easier to invoke Crown Use provisions during the COVID-19 pandemic.

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

The Supreme Court's decision in *Unwired Planet v Huawei and Conversant v Huawei* is expected imminently. This is a very significant and long-awaited ruling on the question of whether it is appropriate to require the taking of a global FRAND licence to avoid a UK injunction which will likely have a huge impact on the mobile telecommunications industry.

We can also expect continuing developments in relation to the proper approach to the application of the UK doctrine of equivalents, following *Actavis v Eli Lilly*, as a result of various appeals currently pending before the Court of Appeal. For example, the Court of Appeal has yet to resolve whether there exists a *Formstein* defence to infringement, i.e. if an accused product or process is an equivalent and for that reason would fall within the scope of the claim, but the equivalent would have lacked novelty or inventive step over the prior art at the priority date, then is it deemed to fall outside the scope of the claim, thus providing a defence to infringement (see also the answer to question 1.19).

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

There has been increasing popularity of the Shorter Trial Scheme (STS) (described in the answer to question 1.9) in a number of patent disputes. In *Facebook Ireland v Voxer IP* [2020] the Patents Court fixed the trial date of an action under the STS in advance of the Case Management Conference (CMC). Under the STS trial dates must be set within 8 months of the CMC unless fixed earlier. Here it was appropriate to fix the trial date five months after the CMC. Although the desire of the alleged infringer to have a decision on the validity of the patent before infringement proceedings in Germany, where validity and infringement are bifurcated, would not on its own have been a ground for an expedited trial, the judge noted that the very purpose of the STS was to achieve shorter and earlier trials at reasonable and proportionate cost. Litigants may therefore choose to take advantage of the philosophy of the STS: to offer earlier trial dates in return for the dispute occupying less of the court's resources.

The Disclosure Pilot Scheme (DPS) (see answer to question 1.5) will be extended for another year to allow for further assessment. It is likely that it will become part of the Civil Procedural Rules albeit in a modified form.

A developing area of both procedural and substantive law is whether, although patent infringement is objective, the test of whether a product falls within a claim under the doctrine of equivalents may have indirectly introduced a mental element akin to copying. If so, this may have a potential impact on disclosure applications and orders.

In line with the issue-based focus of the DPS it is likely that any disclosure orders in patent litigation will focus on specific issues to ensure that searches are proportionate, as in *Merck Sharp & Dohme v Wyeth* [2019].

Finally, the Patents Court in *Evalve v Edwards Lifesciences* [2020] has unequivocally confirmed, in the context of defendants raising the public interest as a defence to patent infringement, that a final general injunction to restrain future infringements is the normal remedy for patent infringement and the onus is on the defendant to give reasons why such an injunction should not be granted. Any refusal or qualification of a patent injunction on public interest grounds should be used sparingly and in limited circumstances.

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