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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 therefore address claims in England and Wales only. Patent infringement proceedings in England and Wales may be brought in the Patents Court (part of the Business and Property Courts of the High Court of Justice) 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 legal costs recoverable by a successful party are capped at £60,000 for the final determination of liability, and at £30,000 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. Alternatively, infringement claims may be brought in the UK Intellectual Property Office (UKIPO), but since injunctions are not available, the jurisdiction is little used.

1.2 Can the parties be required to undertake alternative dispute resolution 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 are 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; following the Court of Appeal's decision in *Churchill v Merthyr Tydfil Country Borough Council* [2023], judges have the power, in appropriate circumstances, to order the parties to participate in ADR and stay the proceedings while they do so.

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, solicitors and patent attorneys also 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 the Claim and, in infringement 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 is mandatory; it is not 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 £569. However, where a claim for injunctive relief includes a claim for unlimited damages, 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; however, few cases in the Patents Court are currently meeting this target.

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. There is a mandatory Disclosure Scheme in the Business and Property Courts, which includes the Patents Court.

Initial Disclosure of key documents that 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

the pleadings. A search should not be required for Initial Disclosure, although one may be undertaken.

After close of pleadings, and before the Case Management Conference, the parties are required to jointly complete a Disclosure Review Document setting out any issues for disclosure and the scope of searching to be done in relation to each issue (referred to as "Extended Disclosure" Models A to E). 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 that may lead to a train of enquiry. The court will be proactive in determining the appropriate Model and need not accept the Model proposed by the parties. The court will only order search-based disclosure (Models C, D or E) where it is appropriate to do so to fairly resolve one or more of the issues.

In *Merck Sharp & Dohme v Wyeth* [2019], the judge accepted that a wide-ranging search would be both costly and disproportionate, but in the circumstances, it was proportionate to order the patentee to search for and disclose laboratory notebooks, internal reports, e-mails, meeting minutes and presentations created, modified or received by the named inventors that provided information relating to a document pleaded in the Grounds of Invalidity.

Unless the court orders otherwise, no disclosure of the following classes of documents will be ordered: (i) documents that relate to infringement where a product or process description is provided (*in lieu*); (ii) documents that relate to validity that came into existence more than two years before or after the earliest claimed priority date of the patent; or (iii) documents that relate to commercial success.

The Disclosure 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, balancing the likely probative value of the documents against the cost or difficulty of the search.

Confidential documents that 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 consist of: (i) service of the Claim Form on the defendant with Particulars of Claim and Particulars of Infringement showing which patent claims are alleged to be infringed and at least one example of each type of alleged infringement; (ii) service of a Defence (and Counterclaim with Grounds of Invalidity, if applicable); (iii) hearing of the Case Management Conference before a judge, at which directions for the further conduct of the action are given, including deadlines for procedural steps and number of experts permitted; (iv) fixing the trial date by the court listing office; (v) service of Notices to Admit Facts and replies, to identify points that are not in dispute; (vi) exchange of document lists and disclosure 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 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, a guide for the judge's pre-trial reading, including a time estimate and bundles of documents (now often in electronic form).

The pre-trial procedure in the IPEC follows the same steps, with the following differences: (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 their claim before commencing the action; (ii) all pleadings must set out concisely all the facts and arguments relied upon; (iii) save in exceptional circumstances (see the answer to question 1.7), the judge will not allow the parties to supplement their pleadings; (iv) there is no disclosure of documents, unless ordered by the judge at the Case Management Conference; 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 Case Management Conference.

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 or agreed statement of common general knowledge (if any); (ix) a guide for the judge's pre-trial reading, including a time estimate; and (x) each party's skeleton argument. The parties are responsible for the preparation of 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 referred to at (ix) in the answer to question 1.6. The advocate for the claimant opens the trial with an address that follows and supplements the skeleton argument. The judge will ask questions for clarification throughout the trial. Increasingly, the defendant's advocate may also give an opening speech. The claimant's advocate then calls the claimant's experts and witnesses to confirm that their written evidence is, indeed, theirs, after which they are cross-examined by the defendant's advocate. At the conclusion of each cross-examination, the claimant's advocate may put questions to the expert or witness by way of re-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 their skeleton argument as necessary in the light of the evidence given to the court. Finally, the claimant's advocate closes the trial with a similar address.

In the IPEC, the court may determine the claim without a trial if all parties consent. If there is a trial, the Enterprise Judge will

determine the amount of time allocated to each party (and for cross-examination of any of the witnesses and experts) and set the timetable, in order that the trial 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. 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 permitted subject to a costs order that 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, meaning that the costs caused by the amendment will have greater significance than in the Patents Court and the costs-benefit analysis of permitting amendments is more thorough. This means that litigants must be more circumspect about being able to amend their case in the IPEC.

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, or there may be no trial at all (i.e. the case is decided upon the papers filed alone, see question 1.7). Judgments are almost always reserved. Although it depends upon the judge and their workload, the average length of time between trial conclusion and handing down of judgment is 75 days (Source: Solomonic).

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?

A case may be allocated to the Shorter Trials Scheme (STS) in which case 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 Case Management Conference, 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 the issue of proceedings, and a judgment will be handed down within six weeks. The main advantage of the STS is its speed compared to normal High Court proceedings. It is similar to the IPEC in its limitation to specific disclosure only. From 1 January 2024, a cap limits costs recovery in the STS to £500,000 for liability and £250,000 for a damages inquiry.

The parties may also agree to the case being allocated to the Flexible Trials Scheme (FTS), which allows them to adapt the trial procedure to suit their particular case. 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.

For technically simple cases, a further alternative option is available in the Patents Court in that either party may apply for an order that the action proceed by way of a "streamlined procedure" where all evidence is in writing and there is no requirement for disclosure. The trial is normally fixed for a date not more than six months after the Case Management Conference and the trial itself is no longer than a day.

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 are 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.

The Royal Courts of Justice currently provide copies of significant judgments to the British and Irish Legal Information Institute (BAILII), for publication on the https://www.bailii.org website and the Copies of judgments are available from the National Archives: Find Case Law (https://nationalarchives.gov.uk).

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 considered persuasive?

In 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 (EPO), particularly the Enlarged Board of Appeal, are not binding but are 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 and deputy judges who have scientific backgrounds, and are normally allocated to cases with a higher technical difficulty rating. Similarly, the judge in the IPEC has a technical background. There are also specialist patent judges in the Court of Appeal.

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. Under the former, any person doing or proposing to do any act may seek a declaration of non-infringement from the court. Under the latter (the court's inherent jurisdiction), there must, in general, be a real and present dispute between the parties as to the existence or extent of a legal right. Although the claimant does not need to have a present cause of action, both parties must be affected by the court's determination.

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 in the answer to question 1.13. 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. If relying on the court's inherent discretion, an application for a declaration of non-infringement must be sufficiently well defined and serve a useful purpose.

The court has wide discretion to grant any form of declaratory relief (whether affirmative or negative) under its inherent jurisdiction. Thus, the Patents Court has been willing to grant negative declarations in favour of mobile telephone handset manufacturers that certain telecommunications patents declared as "essential" to the implementation of certain standards are not, in fact, "essential", as purported by the patent owner (so-called declarations of non-essentiality).

The Court of Appeal in *Mexichem v Honeywell* [2020] confirmed the availability of "Arrow declarations" (named after the case of *Arrow Generics v Merck* [2007] where they were first granted. Arrow declarations are a discretionary remedy that 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 in suit. As and when the patent is granted, the Arrow declaration will operate as a 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 they supply or offer to supply a person in the UK, other than a licensee, with any essential element of the claimed invention when they know, 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. Knowledge of the patent, actual or constructive, is not a pre-requisite for infringement; rather, knowledge of the intended product or process is required. Knowledge of the intention of the ultimate user is also not required, 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 that 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?

Yes, 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 normal or "purposive" interpretation. If infringement is not established on that basis then, following the Supreme Court decision in *Actavis v Eli Lilly* [2017], consideration is given to whether the product infringes because it varies from the invention in a way or ways that is or are immaterial. That question is answered by asking three further questions, namely: (i) does the variant achieve substantially the same result in substantially the same way; (ii) would the functional equivalence be obvious to the skilled person at the priority date (knowing that the answer to question 1 is "yes"); and (iii) did the patentee intend there to be strict compliance with the literal meaning of the claim?

Actavis also raised the question of whether there can be anticipation by equivalence (see question 1.19 below). Although it was rejected in *Generics v Yeda Research and Development* [2017], in *Optis v Apple* [2021], Meade J allowed anticipation by equivalence to be pleaded, while noting the question will need to be considered 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.

A claim or counterclaim for revocation may be raised regardless of whether there is pending opposition.

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

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")?

This issue has only arisen in the UK following the Supreme Court's decision in *Actavis v Eli Lilly* (see answer to question 1.17). Although raised in a few cases, it has only been successful in *Vernacare v Moulded Fibre Products* [2022] where the IPEC Judge held that there was no infringement by equivalence because the patent would have been invalid if it had that scope (a finding which was not disturbed on appeal).

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 permitted; 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 counterclaim for revocation) should be granted pending resolution of validity of the patent in the EPO is a matter of discretion for the court to exercise, addressing whether, on balance, a stay is in the interests of justice. Guidelines were provided by the Court of Appeal in *IPCom v HTC* [2013], which included the following points: (i) if there are no other factors, a stay of the national proceedings is the default option; (ii) the onus is on the party resisting the grant of the stay to adduce evidence as to why it should not be granted; (iii) 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 is an important factor affecting the discretion, this must be considered in conjunction with the prejudice that any party will suffer from the delay; (iv) the judge is entitled to refuse a stay where the evidence is that some commercial certainty would be achieved at a considerably earlier date in the case of the UK proceedings than in the EPO; and (v) in weighing the balance, the risk of wasted costs is material, but will normally be outweighed by commercial factors concerned with early resolution.

The issue of a stay does not arise in practice as between the court and the UKIPO, since any ongoing revocation proceedings before the UKIPO will normally be transferred to the court following the commencement of an infringement action. Further, a decision in relation to a corresponding patent in another country is not binding on the UK court and so an action in relation to such a patent is not a ground for a stay.

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 carried out (or where effective and serious preparations to do such act were carried out) 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 to the defendant as it does not extend to granting a licence to another person to carry out 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 UKIPO 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 that are determined by the court in default of agreement by the parties which, in turn, means that these provisions are hardly used. (In one rare case, *IPCom v Vodafone* [2021], the Court of Appeal overturned the decision at first instance, holding that the Crown use defence did not apply).

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 highly unusual in patent cases. They are heard on an *inter partes* basis and granted if (i) there is a serious issue to be tried; that is to say there is an arguable case, (ii) the "balance of convenience" favours an injunction, and (iii) the claimant gives a cross-undertaking to compensate the defendant in damages if the injunction was wrongly granted. In practice, they are restricted to pharmaceutical cases where a defendant proposes to introduce a first generic product and where the claimant can show that there will be irreparable damage as a result of irreversible price erosion.

Three recent cases have departed from this practice and interim injunctions were refused, therefore permitting the launch of a generic (*Neurim v Mylan* [2020], *Novartis AG v Teva UK* [2022] and *Neurim v Teva* [2022]). In 2022, the Court of Appeal in *Neurim v Mylan* upheld the High Court's decision not to grant an injunction. In *Novartis*, Roth J also accepted that whether there will be an irreparable price spiral (supporting an injunction) is very fact specific. Similarly, in *Neurim v Teva*, Mellor J refused Neurim's application for an injunction, noting there had been significant delay in bringing the application and that the *status quo* at the time of filing was that generic products had already been on the market for several months. However, in *Sandoz v Bayer Intellectual Property*

[2024], the Court took the unusual step of granting an injunction for a nine- to 10-day period between the expiry of the relevant SPC and the expected hand down of judgment addressing validity of the patent and was further extended to allow time for an expedited appeal. Protective letters are not available in the UK.

(b) Final injunctions are almost always granted if the claimant is successful at trial but are a matter for the court's discretion, meaning that flexibility is possible to deal with unusual situations.

(c) The public interest, such as the impact on third parties, is a relevant consideration that 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. In the result, the public interest defence was rejected and the injunction granted with a limited exception to deal with a narrow set of facts.

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/flagrancy damages available?

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 an "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, they can claim (a) lost profits on sales by the defendant which they would otherwise have made, (b) lost profits on their own sales, to the extent that they were forced to reduce their own price, and (c) a reasonable royalty on sales by the defendant which they 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, (ii) appropriate measures for the dissemination and publication of the judgment, at the expense of the infringer, 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 under its inherent jurisdiction. The decision was upheld by the Court of Appeal (*Actavis v Lilly* [2013]). 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.

The Supreme Court held in *Unwired Planet v Huawei* [2020] that the court can settle the terms of a Fair, Reasonable and Non-Discriminatory (FRAND) licence on a global basis where a UK patent was found to have been infringed. The determination of such a licence is part of the defence to the claim for an injunction to the UK patent, and therefore the UK court is considered to be the proper forum.

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

Many patent actions 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.

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 have discovered 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 either the trial judge or the Court of Appeal gives permission. The appeal must have "a real prospect of success", i.e. it must be realistic and credible.

1.30 What effect does an appeal have on the award of: (i) an injunction; (ii) an enquiry as to damages or an account of profits; or (iii) an order that a patent be revoked?

(i) A stay of an injunction pending appeal may be granted on the "balance of convenience" 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.
(ii) An appeal would not normally lead to a stay of the enquiry as to damages or account of profits, unless agreed by the parties.
(iii) An appeal on validity by an unsuccessful patentee will lead to a stay of the order for revocation pending the outcome of the appeal.

1.31 Is an appeal by way of a review or a rehearing? Can new evidence be adduced on appeal?

An appeal is by way of a review, not a rehearing. As such, the Court of Appeal is always reluctant to interfere with findings of fact by the trial judge or with value judgments such as obviousness. New evidence or material is not permitted on appeal unless it could not, with due diligence, have been found for use at the trial, and even then it is only permitted when it is likely to have a material effect on the appeal.

1.32 How long does it usually take for an appeal to be heard?

It takes between 12 and 18 months for the appeal to be heard.

1.33 How many levels of appeal are there? Is there a right to a second level of appeal? How often in practice is there a second level of appeal in patent cases?

There are two levels of appeal from the first instance decision: first to the Court of Appeal (see the answer to question 1.29); and then to the Supreme Court. There is no right to appeal to the Supreme Court; permission must be obtained from either the Court of Appeal or the Supreme Court itself. In practice, permission to appeal patent cases to the Supreme Court is rarely given.

1.34 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? What are the typical costs of an appeal and are they recoverable?

Infringement and validity are dealt with together at the same trial. The typical cost of such an action is in the region of £750,000 to £1.5 million 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. In the Patents Court, parties must 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 that 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.

As a result of the nature of the appeal process, the costs of an appeal are normally considerably less than those at first instance. Cost recovery is dealt with in a similar way to that in the Patents Court. If a decision is successfully appealed, it will open up the decision on the costs awarded at first instance.

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 UKIPO. 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 limitation of a European patent is also possible via proceedings at the 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 permitting it. If the patent owner fails to seek amendment before the patent is revoked at first instance, they will generally be refused permission to amend on appeal, as this is regarded as an impermissible attempt to re-litigate issues that should have been addressed at first instance.

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

The constraints are the same as those that apply under the European Patent Convention; namely, that an amendment will not be permitted if it would extend (i) the subject matter over and above the disclosure contained in the application for the patent, (ii) the extent of protection, or (iii) 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 that limit the terms upon which parties may agree a patent licence?

Yes, UK competition law prohibits terms in a licence that 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.

The UK now has three domestic block exemptions which, despite the UK's withdrawal from the EU, follow their EU counterparts very closely:

(i) the Competition Act 1998 (Vertical Agreements Block Exemption) Order 2022, applying to distribution and supply agreements;
(ii) the Competition Act 1998 (Research & Development Agreements Block Exemption) Order 2022, applying to R&D agreements; and
(iii) the Competition Act 1998 (Specialisation Agreements Block Exemption) Order 2022, applying to specialisation agreements meeting all the specified criteria.

In contrast, the EU Technology Transfer Block Exemption for patent, design, know-how and software copyright licensing continues in force in the UK until 30 April 2026 as retained EU law.

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 answers to questions 1.22 and 1.23(c) 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?

A form of "extension" is available in EU Member States in respect of patents that cover an authorised medicinal or plant protection product called a Supplementary Protection Certificate (SPC). The scope of protection of an SPC is limited to the product as authorised, for a maximum term of five years or 15 years from the authorisation of the product, whichever is the earlier.

Following the UK's exit from the EU on 31 December 2020, UK SPCs granted before that date remain valid, and there is no change as to their term. Under the UK–EU Withdrawal Agreement, all pending SPC applications filed in the UK before 31 December 2020 were examined in the same way regardless of Brexit, and provided the same rights once granted.

Applicants for new SPC applications require a UK patent granted by the EPO or the UKIPO, and a marketing authorisation valid in the UK. Therefore, the application can be based on either: (i) existing European Medicines Agency (EMA) authorisations, if the product has already been authorised by the EMA before 2021 and that EMA marketing authorisation has become a UK marketing authorisation; or (ii) marketing authorisations granted by the UK's Medicines and Healthcare Products Regulatory Agency.

SPC protection is subject to the so-called "SPC manufacturing waiver", which allows UK-based companies to manufacture a generic or biosimilar version of an SPC-protected medicine during the term in which the SPC remains in force (i) for the purpose of exporting to a market outside the UK, Isle of Man and EU, or (ii) for stockpiling during the final six months of an SPC ahead of entry into the UK market (to perform a first day entry after lapse of SPC protection).

5 Patent Prosecution and Opposition

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

In accordance with its obligations under the European Patent Convention 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 computer programs are excluded, as are inventions of which the commercial exploitation 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 European Patent Convention and the EPO.

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 no such requirement either at the UKIPO or the EPO. The EPO 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 EPO 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 under a duty to disclose such prior art, given the decision by the CJEU in Case C-457/10P (*AstraZeneca*).

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?

The only way of doing this post-grant in the UK is to seek revocation either before the court or in the UKIPO. However, the grant of a European patent that designates the UK may be opposed at the EPO within nine months of grant.

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

Yes, an appeal lies with 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 UKIPO. 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?

Yes, six months prior to filing. Under section 2(4) of the Patents Act 1977, there are certain limited exceptions that exclude material disclosed during the six months prior to filing from the "state of the art". The categories of excluded material are: (i) matter that is disclosed due to, or disclosed in consequence of, it having been obtained unlawfully or in breach of confidence by any person, which is directly or indirectly derived from the inventor; and (ii) matter that 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, 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 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.

5.9 For Member States within the European Union: Can a Unitary Patent, on grant, take effect in your jurisdiction? If your Member State has not yet signed or ratified the Unified Patent Court Agreement, is it likely to do so and, if so, when?

No – the UK withdrew from the EU on 31 January 2020.

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. Following the UK's exit from the EU, the Customs (Enforcement of Intellectual Property Rights) (Amendment) (EU Exit) Regulations 2019 now dictate customs measures against goods suspected of infringing IP rights, including goods that infringe a patent or an SPC. These Regulations largely mirror the EU process which governed customs seizures under Regulation (EU) No 608/2013. From 1 January 2021:

- pre-existing EU applications for action (AFAs) filed via the UK's HM Revenue & Customs will remain valid and enforceable in the UK but will cease to have effect in the 27 EU Member States;
- pre-existing EU AFAs filed in the 27 EU Member States will cease to have effect in the UK; and
- to obtain protection in the UK, the national system must be followed and an AFA must be filed online with HM Revenue & Customs.

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.

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 set FRAND terms (or would they do so in principle)? Do courts grant FRAND injunctions, i.e. final injunctions against patent infringement unless and until defendants enter into a FRAND licence?

In *Unwired Planet v Huawei* [2020], the Supreme Court held that courts in the UK can settle the terms of a FRAND licence on a global basis, where a UK or GB patent was found infringed. Since the underlying claim was for infringement of a UK patent, the court was the proper forum even if the UK constituted only a minority of the defendants' global sales. The Supreme Court agreed with Unwired Planet's arguments that companies in the mobile telephony industry did not negotiate licences on a country-by-country basis, and therefore it was commercially unrealistic to determine a licence for only a single country in determining FRAND terms. The European Telecommunications Standards Institute (ETSI) policy, from which the obligation for FRAND licensing derived, empowered a national court to determine the terms that were FRAND and this therefore included determination of terms on a global basis. Since then, the UK courts have, in *InterDigital v Lenovo* [2023] and in *Optis v Apple* [2023], set the rate(s) for a FRAND licence and a number of other FRAND cases are in the pipeline.

Where an implementer has been held to infringe a SEP and refuses to enter into a FRAND licence, the courts will grant an injunction to restrain infringement in the UK (a so-called FRAND injunction). The implementer must make the election at the time they are found to infringe, even if the terms of the FRAND licence have not, at that time, been determined (*Optis v Apple* [2022] Court of Appeal – the parties settled before the appeal to the Supreme Court was heard).

In the UK, technical trials dealing with validity and infringement have until recently been heard separately from and before proceedings relating to FRAND licensing issues on the basis that a finding of infringement is an essential stepping stone in the process. However, recently, the judges have indicated that the FRAND issues should be prioritised, for example, scheduling a single trial or two trials (one technical, one FRAND) very close together.

8 Current Developments

8.1 What have been the significant developments, including any leading cases, in patent law and practice in your jurisdiction in the last year?

In the life sciences area, as we highlighted previously, the Court of Appeal in *FibroGen Inc v Akebia Therapeutics* [2021] established a "reasonable prediction" approach to determining the sufficiency and plausibility (i.e. enablement) of claims to broad classes of compounds defined in part by their function. This approach was widely considered to be something of a departure from the requirement that a patent must be sufficiently enabled across the entire scope of the claim. The Supreme Court was due to hear the appeal in *FibroGen Inc v Akebia Therapeutics* in early 2024; however, the case settled, leaving the Court of Appeal's decision as the leading case for the foreseeable future. It is worth noting, however, that courts in subsequent cases (*Teva Pharmaceutical Industries v Grünenthal* [2023]; *Sandoz v Teva Pharmaceutical Industries* [2023]) have considered that the "reasonable prediction" approach is only applicable to the circumstances of *FibroGen* (i.e. a broad Markush claim, with a limitation to compounds that achieve a particular therapeutic effect), so in practice, it may be that the relevance of *FibroGen* diminishes over time.

Also in life sciences, the Court of Appeal in *Sandoz AG v Bayer Intellectual Property* [2024] considered the somewhat unusual idea that ethical considerations could form the basis of the skilled team's reasonable expectation of success in assessing obviousness. The case concerned whether Bayer's patent for a once-daily administration of rivaroxaban for the treatment of thromboembolic disorders was obvious in light of conference publications reporting on successful phase I trials. The judge at first instance found that there was no technical barrier to introducing a once-daily dosage regimen, but it was also relevant to consider whether an ethics committee would give permission for a phase II trial when assessing whether the skilled team would expect the regimen to be safe and effective. This was particularly relevant because there was uncertainty around the therapeutic window for rivaroxaban and dosing outside of that window risked harming patients. Despite this, the court ultimately found the patent obvious over the prior art. On appeal, the Court of Appeal rejected the idea that ethics committee approval was relevant to whether there were reasonable prospects of success, noting that this is a strictly technical assessment. However, the safety issues considered at first instance would effectively form part of the question of whether the dosage regimen was safe and effective, so although the judge's approach was not correct, the Court of Appeal's conclusion was that the patent was obvious.

In an interesting development in the ongoing battle around mRNA vaccine technology, the court considered in *Pfizer v Moderna* [2024] that the "pledge" made by Moderna in October 2020 that it would not enforce its COVID-19 vaccine patents "while the pandemic continues" could form the basis of a defence to patent infringement. Richards J held the pledge amounted to consent to use Moderna's patents. It was not necessary that someone was infringing or knew they were infringing to be covered by the consent. Moderna's subsequent statement in March 2022 revoking the pledge was sufficient to withdraw consent, regardless of whether the pandemic period had ended. Accordingly, Pfizer was entitled to rely on the pledge for the period between October 2020 and March 2022 as a defence to otherwise infringing activities.

In relation to SEP/FRAND patent litigation, of note this year has been the Court of Appeal's decision in *InterDigital v Lenovo* [2024] in which the Court of Appeal held that the judge had failed to take into consideration the heavy discounting which had been forced on InterDigital and other SEP owners in negotiations with implementors when deriving the blended rate from the closest comparable licence when determining what rate Lenovo should pay for use of InterDigital's cellular SEP portfolio. Since neither side suggested remitting the matter to the judge, the Court of Appeal imposed its own estimate of $0.225/unit in place of the $0.175/unit determined by the judge. However, the Court of Appeal upheld the judge on two key issues: (1) that limitation was irrelevant to the determination of FRAND and that Lenovo should pay royalties for all the past sales they had made; and (2) that Lenovo should pay interest on those past royalties.

As we highlighted in last year's chapter, the Supreme Court heard the final UK appeal in the series of cases brought by Dr Thaler in relation to the AI entity, known as DABUS (standing for a Device for the Autonomous Bootstrapping of Unified Sentience) on 2 March 2023 (*Thaler v Comptroller-General of Patents, Designs and Trademarks*). On 20 December 2023, the Supreme Court handed down its highly anticipated decision, finally determining that: (a) an inventor must be a natural person, so an AI system such as DABUS could not be an inventor; (b) the doctrine of accession did not entitle the owner of an AI system to apply for patents purportedly produced by the AI system; thus, Dr Thaler was not able to apply for patents produced by DABUS; and (c) as a result of (a) and (b), the UKIPO was entitled to treat Dr Thaler's patent applications as withdrawn for failing to identify a person who was the inventor and failing to demonstrate Dr Thaler's entitlement to the invention. The Court emphasised that this outcome flowed from the current form of the Patents Act 1977 and the question of whether inventions made by AI systems should be patentable in future would need to be addressed by Parliament.

8.2 Are you looking forward to any particular developments in patent law or practice in the coming year or two and what effect might they have in your jurisdiction?

Continuing the theme of AI and machine learning, the Court of Appeal has, for the first time in many years, considered the exclusion from patentability of computer programs in *Emotional Perception AI v Comptroller-General of Patents, Designs and Trade Marks* [2024]. Emotional Perception AI filed a patent application related to a method for an artificial neural network (ANN) to make improved media recommendations based on human perception and emotion. The UKIPO rejected the application on the basis that it related to "a computer program… as such", which is excluded subject matter under section 1(2) of the Patents Act 1977. The decision was reversed on appeal to the Patents Court. The Court found that the computer exclusion in section 1(2) was not invoked at all because the operation of the trained ANN did not involve a computer program as it was not implementing a series of instructions pre-ordained

by a human, rather it was operating according to something it had learned for itself. In the event he was wrong, the Judge held that the trained ANN produced a technical effect outside of the computer program by sending the recommendation, so would not be excluded from patentability. The Court of Appeal allowed the appeal. The computer exclusion was invoked since the ANN was "clearly a computer – it is a machine for processing information". The set of weights and biases (parameters which are adjustable during training) of the ANN formed the computer program, irrespective of whether it was a hardware ANN or a software ANN. Section 1(2) was therefore engaged. The next question was whether there was a technical contribution in sending the recommendation. Here, the Court of Appeal again differed from the Judge. What made the recommendations worthwhile were the semantic qualities that were subjective and cognitive in nature and not technical matter at all. Although, as noted by the Judge, the system had gone about its analysis and selection in a technical way, that was because it was an ANN, i.e. a computer, and did not impact the fact that this aspect of the contribution (providing improved file recommendations) was non-technical in quality. In coming to this conclusion, the Court of Appeal noted that its view was consistent with that of the EPO's Technical Board of Appeal in *Yahoo!* T0306/10. Considering the potential impact on the booming AI sector, this decision is of considerable importance.

The UK High Court, as one of the few that will determine a FRAND licence, has been extremely busy with cases in which either the patent owner or the implementer seeks a FRAND licence and this looks set to continue in the next few years. However, longer term, two efforts to develop more consistent approaches to SEPs across a number of jurisdictions may impact the way cases are currently handled. In the first, in April 2023, the EU Commission proposed a draft regulation on SEPs. The proposal would give the European Intellectual Property Office (EUIPO) responsibility for maintaining a register of SEPs, standards and details relating to aggregate royalty rates. The EUIPO would also maintain a process for assessing essentiality of SEPs and determining FRAND licensing terms. The draft regulation is progressing through the European Parliament, with the European Economic and Social Committee providing its opinion in September 2023 and the Legal Affairs Committee in January 2024, with some amendments recommended. On 28 February 2024, the European Parliament voted in favour of the amended draft regulation. The draft regulation must now be approved by the European Council; however, European Parliament elections in June 2024 may delay progress. Accordingly, the final passage and potential implementation of the regulation will be watched with interest in the coming year.

Separately, on 3 June 2024, the USPTO and UKIPO signed a memorandum of understanding (MoU) intended to provide a framework for closer collaboration between the US and UK in developing policies relating to SEPs. The MoU will last for five years and, although the terms will not be made public, it relates to:

- facilitating collaboration and exchange of information on SEP policy to ensure a better-balanced standards ecosystem;
- exploring means to educate small and medium-sized enterprises seeking to implement or contribute to the development of technical interoperability standards on FRAND terms;
- examining ways to improve transparency in licensing of standards on FRAND terms;
- engaging in outreach to raise awareness of issues relating to SEPs; and
- discussing means to incorporate additional jurisdictions into the USPTO and UKIPO's activities relating to SEPs.

Although it is unclear at this stage whether the MoU will result in any changes in the short term, the commitment by the USPTO and UKIPO to work together and more closely align SEP policy in the US and UK may lead to some interesting developments in the coming year and will be keenly watched.

Moving back to life sciences, on 28 February 2024, the European Parliament also adopted four proposed SPC regulations – two relating to unitary SPCs for medicinal and plant protection products and two updating existing SPC regulations. The draft regulations had been initially proposed in April 2023 and amended following recommendations from the Legal Affairs Committee in January 2024. The draft regulations must now be approved by the European Council; however, this may also be delayed by the European Parliament elections.

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

The Patents Court continues to be extremely busy, with the time to trial still regularly exceeding the Court's target of 12 months; however, timelines are starting to come down. Over the last year, the Court has allocated patents cases to a number of judges outside of the specialist judges permanently allocated to the Patents Court, which has assisted in reducing the backlog of cases. Similarly, the Patents Court also continues to make substantial use of deputy judges to assist in bringing case timeframes down. Overall, the average time between trial and judgment has remained constant at approximately 75 days, although this is still well above the long-term average of 44 days (source: Solomonic).

Judges continue to take an active role in case management. Judges have also commented in a number of cases on the role of expert evidence and how experts should be instructed, particularly when involved in proceedings in multiple jurisdictions, suggesting this is an area the Courts are likely to scrutinise more closely going forward.

8.4 Are there any key issues in relation to patent law or practice that you feel are not addressed by the questions above which are worth mentioning here?

After a full year of the UPC being in operation, an area to watch is the developing dynamic between the UK courts and the UPC and the strategies employed by litigants to make the most of the strengths of both systems. One approach that has arisen in several recent cases is to seek expedition of cases in the UK where there are parallel proceedings in the UPC. This is similar to the strategy previously employed in relation to parallel proceedings in the UK and German national courts to mitigate some of the effects of the German "injunction gap". Two recent decisions (*Texas Instruments v Network Systems* [2024]; *Samsung Bioepis UK v Alexion Pharmaceuticals* [2024]) considered the extent to which parallel proceeding in the UPC could justify expedition in the UK. In both, expedition was granted (in *Texas Instruments*, it was granted in principle unless the parties agreed to suitable undertakings); however, Meade J emphasised that the parallel UPC proceedings were, at most, a secondary consideration that could not by itself justify expedition. This is in line with the general position of the UK courts

that wanting a UK judgment to deploy in foreign proceedings does not justify expedition; however, Meade J also noted that the lack of an injunction gap in the UPC further weakened any argument about the benefit of having a UK judgment available.

On 27 June 2024, the UK ratified the Hague Convention on the recognition and enforcement of foreign judgments in civil and commercial matters. The Convention provides a framework for the mutual recognition and enforcement of civil and commercial judgments between contracting states (including all EU Members except Denmark). The Convention will enter into force in the UK from 1 July 2025 and will apply to proceedings commenced after that date.

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