

**International
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Legal Guides**



Practical cross-border insights into patent law

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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 £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. (From 1 October 2022, the costs caps are to increase to £60,000 and £30,000, respectively.) 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 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 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.

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 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 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 £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.

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 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 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 setting out the issues, if any, for disclosure and the scope of the 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 directing which is the appropriate Model and need not accept without question 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 in order 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 (*in lieu*) a product or process description is provided; (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 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 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 of the claims of the patent are alleged to be infringed, with 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 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 follows the same steps, save that it differs 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 their 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 1.7), 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 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 (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 that 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/her 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 that supplements his/her skeleton argument in the light of the evidence. In the IPEC, the court may determine the claim without a trial if all parties consent. If there is a trial, the Enterprise Judge will determine the amount of time

allocated to each party (and for cross-examination of any of the witnesses and experts) and set the timetable, 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 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 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, similarly, 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; 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 Trials Scheme (STS) was adopted permanently in the Business and Property Courts (of which the Patents Court is part) 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 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 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 are willing to refuse applications to transfer out where cases are deemed suitable. Where, however, complex patent 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 by the Business and Property

Courts, allows parties by agreement to adapt the 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 that 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 available in the Patents Court in that either party may apply 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 Case Management Conference.

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. 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 <http://www.bailii.org> website and, since 2022, to the National Archives.

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 (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 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. 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.
- (ii) 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 had 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 in 2007). 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. Although it was rejected in *Generics v Yeda Research and Development* [2017], in *Opis 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. 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 for revocation, pending an 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). There have, so far, been three decisions at first instance, most recently *Facebook v Voxer* [2021], where the courts have recognised *Formstein* as a possible way forward, but to date no court has actually had to confront the issue. In the Facebook case, the judge, Lord Justice Birss (a judge of the Court of Appeal) commented that, if he had had to decide the matter, he would have held that the *Formstein* approach was the right approach, so that the conclusion if the equivalent device lacked novelty or was obvious, was that the claim scope had to be confined to its normal construction.

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 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? (Please cross-refer to your answer to question 3.2 if compulsory licensing may be available in this scenario).

- (a) Preliminary (interim) injunctions are available and are 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 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 (iii) 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 first 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. Two recent cases have departed from this practice and interim injunctions were refused, therefore permitting the launch of a generic (*Neurim v Mylan* [2020] and *Novartis AG v Teva UK* [2022]). The Court of Appeal upheld the *Neurim* decision but stated that, whilst they agreed with the judge’s reasoning, they “had not decided any principle of general application”. In *Novartis*, Roth J also accepted that whether there will be an irreparable price spiral (supporting an injunction) is very fact specific.

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 (see (c) below). Article 3(2) of the Enforcement Directive 2004/48/EC, which requires the court to refuse to grant an injunction where it would be “disproportionate” to grant one, is also relevant. Case law confirms that 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) 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 (in compliance with the UK’s obligations under the Enforcement Directive 2004/48/EC), 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.

In a much-anticipated decision, 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 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 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 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.

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, 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.
- (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 £1,250,000 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. 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 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.

1.35 For jurisdictions within the European Union: What is the status in your jurisdiction on ratifying the Unified Patent Court Agreement and preparing for the unitary patent package? For jurisdictions outside of the European Union: Are there any mutual recognition of judgments arrangements relating to patents, whether formal or informal, that apply in your jurisdiction?

The UK had ratified the Unified Patent Court Agreement (UPCA), but withdrew this ratification in 2021 as a consequence of Brexit (although at one stage, there was a possibility that the UK might still participate in spite of Brexit).

Following Brexit, as of 31 January 2020, the UK is no longer a party to the Brussels or Lugano Conventions. By virtue of the UK-EU Withdrawal Agreement, the UK continued to apply the Brussels and Lugano regimes to court proceedings instituted

prior to 31 December 2020 (which was the end of the transition period). Therefore, judgments from EU Member States in these proceedings may still be enforced in the UK under the Recast Brussels Regulation (Council Regulation (EU) 1215/2012).

The UK applied to re-join the Lugano Convention in its own right in April 2020; however, this requires consent of all EU Member States and the EU itself, which has not so far been granted. As a result, there is no established mutual recognition or enforcement system in place for proceedings commenced after 31 December 2020, although the Hague Convention may apply where there is an exclusive jurisdiction clause in favour of the English courts. Outside of any established regime, UK courts may consider judgments of foreign courts persuasive in patent cases, but do not have any obligation to recognise or follow those decisions.

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 amendment of the UK designation of a European patent, in accordance with the European Patent Convention, 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 which 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.

Distribution and supply agreements are governed by the Competition Act 1998 Vertical Agreements Block Exemption Order 2022 (SI 2022/516), which replaces the EU block exemptions that were preserved after Brexit by the Competition (Amendment, etc.) (EU Exit) Regulations 2019 (SI 2019/93). The 2022 Order has been drafted with digital business in mind and has clarified the criteria for assessing online intermediation services.

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 that 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 Member State by filing an application with the relevant Patent Office within six months of the grant of the first marketing 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.

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 Withdrawal Agreement, all pending SPC applications filed in the UK before 31 December 2020 are being examined in the same way regardless of Brexit, and provide the same rights once granted.

From 1 January 2021, the UK's SPC regime remains largely unchanged. By virtue of the Patents (Amendment) (EU Exit) Regulations 2019, all EU SPC law was transposed into UK national law, but to make this retained EU legislation work in practice, some processes have had to change. From 1 January 2021, new SPC applications are filed by submitting an application to the UKIPO. Applicants for new SPC applications require (as before) 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 by virtue of the grandfathering introduced to ensure that authorised products remained on the UK market; or (ii) marketing authorisations granted by the UK's Medicines and Healthcare Products Regulatory Agency.

The procedural changes have been made more complex because of the Northern Ireland Protocol which provides that Northern Ireland continues to be aligned, post-Brexit, with the EU in relation to medicinal products. The previous SPC system was not designed to accommodate marketing authorisations that cover only part of the UK. As a result, new legislation

has had to be introduced (Supplementary Protection Certificates (Amendment) (EU Exit) Regulations 2020) to replicate, as far as possible, a regime as familiar as feasible to the previous regime whilst adjusting to the new system of marketing authorisations with a different territory scope.

The amendments made by the Patents (Amendment) (EU Exit) Regulations 2019 are written to have the same meaning as the original EU legislation, so that the existing case law of the Court of Justice of the European Union (CJEU) still applies. However, it is no longer possible for courts in the UK to make references to the CJEU for interpretation of the SPC legislation. It therefore remains to be seen whether and to what extent the courts in the UK will continue to apply new CJEU decisions regarding the interpretation of the EU SPC Regulation to the equivalent UK legislation.

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 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. 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?

Under the European Patent Convention, and correspondingly in the UK under section 2(4) of the Patents Act 1977, there are certain limited exceptions that remove from the "state of the art" material which would otherwise form part of it. In the UK, the following, disclosed during the six months prior to filing, is so excluded: (i) matter which 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 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, 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 jurisdictions within the European Union: Once the Unified Patent Court Agreement enters into force, will a Unitary Patent, on grant, take effect in your jurisdiction?

No. The UK has withdrawn its ratification of the UPCA – see question 1.35 above.

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 the UK, technical trials dealing with validity and infringement are heard separately from proceedings relating to FRAND licensing issues. The judges have indicated in an increasing body of case law that they will look to resolve the dispute as speedily as possible.

In the much-anticipated decision 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. Further, the court would grant an injunction to restrain infringement in the UK where a defendant who had been found to infringe a standard essential patent (SEP) refused to enter into a licence on the terms found by the court to be FRAND (a so-called FRAND injunction).

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 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.

8 Current Developments

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

How patent systems should deal with inventions devised by AI has been an increasingly important and controversial issue over the past year in the UK and internationally.

In *Thaler's Patent* [2020], the UK Patents Court held that an inventor must be a natural person and an AI entity could not be named as an inventor. The judge did not make any finding as to whether or not the AI entity in question, known as DABUS (standing for a Device for the Autonomous Bootstrapping of Unified Sentience), had in fact performed the activity that was claimed as an invention in the patent application. In September 2021, the Court of Appeal upheld the decision, confirming that the Patents Act 1977 requires the inventor to be a natural person. The Court of Appeal also concluded there was no rule of law that new intangible property produced by tangible property is owned by the owner of that tangible property. Accordingly, Dr Thaler would not have been entitled to apply for the patent on the basis of his ownership of DABUS. There was a strong dissenting judgment from LJ Birss and Dr Thaler's team is reportedly seeking leave to appeal to the Supreme Court.

In other developments, the Court of Appeal in *FibroGen v Akebia* [2021] has continued to refine the principles for determining insufficiency following the decisions of the Supreme Court in *Regeneron v Kymab* [2020] and the Patents Court in *Illumina v Latvia MGI* [2021]. *FibroGen* considered how the principles of *Regeneron* applied to determining if a claim with a functional limitation was sufficient in that the skilled person could make a reasonable prediction that the invention would work across substantially the entire breadth of the claim. The Court found that a claim including a mix of structural and functional features (e.g. a Markush formula and a therapeutic use) would be sufficiently described if it was possible for the skilled person to identify if any given compound in the class satisfied the functional limitation. Importantly, it is not necessary for a skilled person to be able to identify all the compounds within the scope of the claim, provided it was possible to determine, without undue burden, if a particular compound fell within the scope.

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

Following the publication of the Government's Call for Views on AI and IP in March 2021 and the National AI Strategy in September 2021, a further consultation on "Artificial Intelligence and IP: copyright and patents" was opened in October 2021. The consultation sought further views on three specific areas identified from the Call for Views:

- (1) if and how should copyright protect computer-generated works without a human author;
- (2) licensing or copyright exceptions for data mining; and
- (3) if and how AI-devised inventions should be patent protected.

Submissions for the consultation closed on 7 January 2022. In June 2022, the Government published the results of the consultation. It decided that no changes will be made to the UK's patent inventorship criteria or copyright provisions for computer-generated works at this time. It said it "will keep AI technical development under review to help ensure that UK

inventorship rules continue to support AI innovation and will seek to advance discussions internationally to support the UK's economic interests". However, there will be some changes to the data mining provisions.

At the end of last year, the Government issued another Call for Views on the question of whether the framework surrounding SEPs is functioning efficiently and strikes the right balance for all entities involved. The Government's stated aim is to provide a framework that will promote innovation and creativity. The Call for Views closed on 1 March 2022 and the Government is currently considering the responses.

Another area under consultation in the past year is the exhaustion of rights. When the UK left the EU, the Government put in a place temporary measure for the exhaustion of intellectual property rights. It had to accept that, having left the EU, rights in goods put on the market in the UK would no longer be considered exhausted in the EEA and could be stopped at the border by the rights' holders. Where the Government had the freedom to decide, it provided that the rights in goods put on the market in the EU would continue to be exhausted in the UK. This unilateral acceptance of an asymmetric regional EEA exhaustion regime is now being called the "UK+" regime. In the absence of any reciprocity, this was the closest way to preserve the *status quo*. However, it was always intended to be a short-term measure pending a decision on what regime should be implemented on a permanent basis. The consultation closed in August 2021, receiving 150 responses from businesses, trade associations and private individuals on the four possible options under consideration:

- retaining the UK+ regime;
- adopting national exhaustion;
- adopting international exhaustion; or
- adopting a mixed regime, i.e. the ability to parallel import will differ as between different intellectual property rights or goods or sectors.

In January 2022, the Government announced it had completed an initial analysis of the responses, but did not have enough data to assess the economic impact of the proposed alternatives to the existing UK+ regime. It said that there will be further development of the policy framework and a decision regarding the approach to exhaustion of IP rights going forward, although no timeframe has been provided as yet. As there are different and competing views amongst industry on the most appropriate regime, and many respondents on balance favoured the current "UK+" for stability, it seems unlikely that there will be any significant developments in the short term.

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

The Patents Court has been extremely busy, which has meant that the time to trial has been edging upwards from the Court's target of 12 months. Consequently, last year saw a number of applications for expedition as the parties sought to "jump the queue". However, as Birss J (as he then was) pointed out in *Nicoventures v Philip Morris* [2020], any such attempt needs to be properly justified and must not interfere with the good

administration of justice. Further, the mere wish for commercial certainty is not enough to justify expedition, nor is the desire to avoid the "injunction gap" that can arise under the bifurcated system in Germany. Expedition was ordered in *Teva v Janssen* [2021], *Neurim v Mylan* [2021] and *Advanced Bionics v MED-EL* [2021], but the application was refused in *Abbott v Dexcom* [2021]; and in *Philips v Xiaomi* [2021], the parties accepted that expedition could not be achieved.

The appointment, therefore, of three highly experienced patent practitioners as Deputy High Court judges in September 2021 was therefore to be welcomed. They are Michael Tappin KC, Charlotte May KC and Campbell Forsyth.

Although all coronavirus restrictions have now been lifted in the UK, the courts continue to operate with a range of remote and hybrid hearing options, including:

- Fully remote hearings, with the judge at home.
- Remote hearings, with the judge in their office or court.
- Hybrid hearings, with the judge and some participants in court, and some participating remotely via video link.
- Normal physical hearings, in which all the participants attend court in person.

The decision as to which type of hearing is appropriate in a particular case will be a judicial decision, although the courts will generally take note of parties' preferences. Current guidance from the Business and Property Courts, including the Patents Court, states that generally all hearings of under half a day will take place remotely. Longer hearings are now generally taking place in person, although it is open to the parties to apply for a hybrid or remote hearing if necessary.

The Patents Court has shown a continuing willingness to contemplate *Arrow* type-declarations (see also question 1.14 above). In *Philip Morris v Nicoventures* [2022], the Court permitted a late amendment to PMI's pleadings to include an *Arrow* declaration, noting that the jurisdictional threshold for such declarations was low. Following on from the decision in *Mexichem v Honeywell* [2020], where the Court of Appeal held that there was no threshold requirement for a party seeking an *Arrow* declaration, or need for a fully formulated product description, the decision in *Nicoventures* further highlights that the Court is prepared to take a very broad and flexible approach to applications for *Arrow*-type declarations.

There have been several recent cases highlighting the seriousness with which the courts view the embargo on disseminating information from draft judgments prior to handing down. It is common practice for the UK courts to provide the parties with a draft judgment for the correction of errors under Practice Direction 40E, subject to strict prohibitions on disclosure or taking action based on its contents. In *Optis v Apple* [2021], an apparent leak of a draft judgment to a third party triggered a significant investigation and ultimately a separate judgment on the issue. Although it was ultimately determined that there had been no breach of the embargo, as only the date for the formal hand-down of the judgment had been shared, the judge was highly critical of how the apparent leak was handled. Similarly, in *Match v Muzmatch* [2022], providing a press release to journalists during the embargo prompted an investigation and separate judgment from the court. Although ultimately no further action was taken, this case and *Optis* highlight the seriousness with which the court views confidentiality around draft judgments.



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